1845 E Southern Avenue, Tempe, AZ85282 (480) 838-3385

January 7, 2011

Director Will Humble
Arizona Department of Health Services
150 N 18th Avenue
Phoenix, AZ85007

Re: Comments on Informal Draft Rules for Medical Marijuana

Dear Director Humble:

On behalf of the Arizona Pharmacy Alliance (AzPA) the comments below follow our review of the Informal Draft Rule language published by your Agency regarding implementation of the Medical Marijuana Initiative (Proposition 203). The Arizona Pharmacy Alliance is the only organization in the state that represents pharmacy professionals, including: pharmacists, pharmacy technicians and student pharmacists Our mission is to provide optimal patient care, foster safe and effective medication therapy, promote innovative practice, and empower members to serve the health care needs of the public.

Changes to State Law are Inconsistent with Federal Law

Any law which bypasses the normal approval and distribution process for medications, including the State regulated drug distribution system and licensed pharmacies, is of grave concern to AzPA Since the new Arizona law allows marijuana use for medical purposes, it should be treated as a medication To support the safe distribution and use of medical marijuana, AzPA supports changes to federal law that would re-classify marijuana from a C-I to C-II so that it could legally be prescribed by medical and nursing providers and managed by pharmacists through licensed pharmacies Support for reclassification should not be construed as support for the use of medical marijuana as a means to treat specific health conditions since marijuana does not have a USP monograph nor is it approved by the FDA. It is simply a pragmatic recognition that more and more states are beginning to allow use of marijuana within a medical context AzPA commits to raising this issue with national pharmacy organizations and the Arizona Congressional delegation. Until federal law allows marijuana to be legally managed by pharmacists and licensed pharmacies, AzPA strongly recommends that pharmacists avoid direct involvement with activities related to the dispensing of marijuana to avoid violations of Federal law that may place professional licensure and participation in Medicare and Medicaid at risk.

Prescription Drug Monitoring Program

AzPA recommends that licensed users of medical marijuana be identified in the State of Arizona's Prescription Drug Monitoring Program (PDMP) database, which is already available to health care professionals who need to know about controlled substance use to protect the safety of the patients they treat Although ADHS has proposed its own database, your Agency's initiative only permits law enforcement officials access By requiring dispensaries to report medical marijuana dispensing to the State's PDMP database, health care professionals are able to facilitate safer treatment options for their patients.

Pharmacists are Medication Experts.

Although AzPA is concerned about the dispensing of marijuana by pharmacists, AzPA recommends pharmacists' involvement in the care of the patients receiving medical marijuana to ensure safe and effective use. The Institute for Safe Medication Practices, in a document entitled, *Protecting U S. Citizens from Inappropriate Medication Use*, writes that pharmacists are uniquely positioned to provide solutions to the problem of medication misuse. Pharmacists are widely accessible and have the ability to improve care, enhance communication among healthcare providers, and optimize medication use, resulting in better patient outcomes. Pharmacists also can help eliminate unnecessary healthcare costs through medication therapy management (MTM), which involves reviewing and monitoring medication use, counseling patients, and conducting wellness and disease-prevention programs. Engaging the pharmacist as a resource for ensuring safe medication use will greatly improve the health of the patient.

Since the rules do require patient education and a medical director, AzPA recommends that the rules should also require that a pharmacist provide medication therapy management services at least annually, including a comprehensive medication review which would include a review of medication history, including all prescription and non-prescription medications and supplements that the qualifying patient is currently using. Since medical marijuana use is approved for qualifying patients with complex illnesses, the risk for drug-drug and drug-condition interactions is significant. MTM services will ensure safe medication use as well as detection and management of adverse drug reactions related to medical marijuana. The pharmacist could easily provide these clinical services through a collaborative practice agreement with the medical director. This team approach is necessary to prevent unforeseen complications and unnecessary costs associated with adverse drug events, especially new adverse drug events associated with the addition of an understudied substance to the patient's medication regimen. Reducing health care expenses through medication misadventure avoidance should be a top priority of the Agency.

Finally, many patients that receive medical marijuana as outpatients will not be able to continue their therapy if admitted into the hospital because of smoking bans in Arizona facilities. We recommend that health-systems and hospitals work with their pharmacists to develop protocols to address the absence of marijuana during the acute and long term in-patient stay.

Quality Assurance

Now that marijuana is purported to treat medical conditions, it should be regulated as a medication. Pharmacies follow USP guidelines for the preparation and dispensing of medications. When pharmaceuticals are compounded by pharmacies, the pharmacist routinely sends compounds for testing on a regular basis to ensure accuracy and safety of the medication. As such, dispensaries and growers should be required to have each "lot" or "batch" tested for percentage of THC to appropriately label the strength of the medication. This practice is necessary to prevent overdoses and unwanted drug-drug interactions. In additional, it would emphasize that Arizona intends to treat the marijuana as medication rather than a recreational drug. Under the proposal drafted by your Agency, marijuana is only measured by weight without regard to dose. With traditional medications, volume and weight do not always translate to dose or potency. It is common knowledge that the level of THC in 2.5 oz of marijuana vary greatly depending on the type of plant and preparation of the plant. The draft rules do not make any distinction in this area and do not require such disclosure. Proper labeling would allow a physician to recommend marijuana to their patient with a specific THC dose, thus ensuring patient safety. Use of THC in food or cigarettes should also require similar labeling.

Dispensaries Oversight

To ensure safety to the public at large, AzPA strongly recommends that dispensaries be held to an equally high standard of quality and safety regulations as pharmacies. Pharmacies are required to comply with copious Federal and State statutes and regulations overseen by the Arizona State Board of Pharmacy. Likewise, medical marijuana dispensaries should be routinely inspected and held to similar standards by ADHS.

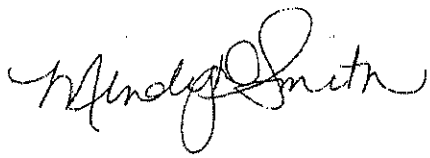
AzPA recommends that ADHS only approve permits for dispensaries that publish policy and procedures focused on patient safety, quality assurance standards focused on product quality, and provide accurate methods to label dosing. Policies and procedures must include a mechanism (managed by the Medical Director and Clinical Pharmacist) to assess the effect medical marijuana has on a patient's other medical conditions, safety, pharmacokinetics, and efficacy of concurrent medications. Your regulations must ensure that each dispensary has policies and procedures that address inventory control, qualifying patient recordkeeping, security, patient education, and prevention of fraud, waste & abuse.

Post Marketing Surveillance

As with all medications, new unpredicted adverse effects can present after widespread public use (e.g. Vioxx). Since medical marijuana has not been reviewed for safety or efficacy by the FDA, the risk for unpredicted adverse events may be greater. Consequently, AzPA recommends that ADHS implement post marketing surveillance through pharmacists at the Arizona Poison and Drug Information Center at The University of Arizona to track adverse drug events and monitor quality, safety and efficacy.

Thank you for the opportunity to submit public comments. Please do not hesitate to call if you have any questions.

Respectfully Submitted,



Mindy D. Smith, BSPharm, R.Ph.
Chief Executive Officer

Arizona Medical Marijuana Association

[redacted]

January 7, 2011

Will Humble
Director
Arizona Department of Health Services
150 North 18th Avenue
Phoenix, AZ 85007

Dear Director Humble:

The Arizona Medical Marijuana Association is pleased to present its comments to the draft rules issued by the Arizona Department of Health Services that will guide the implementation of Proposition 203, the Arizona Medical Marijuana Act

The AzMMA recognizes the major responsibility entrusted in the Arizona Department of Health Services and the complexity of the tasks it must complete within an aggressive time frame called for under Prop 203. We are confident that the Department is and will continue to carry out a public process that will respect the needs and balance the interests of industry professionals who aspire to meet patient needs, prospective patients, and the general public.

The leaders of the AzMMA played a leading role in the drafting of the initiative, and carried out the campaign that led to its passage. Throughout our two year effort, we remained committed to the goal of nothing less than creating the best medical marijuana program in the nation, learning from both the best practices as well as the mistakes made in 14 other states nationwide where medical marijuana laws have been adopted. With only 125 dispensary licensees available, there is no reason to settle for anything less, and the public will demand nothing less. After all, Prop 203 was approved by the slimmest of margins and will remain a controversy for years to come, particularly if it is not implemented properly

At this still early stage, the process undertaken by DHS appears to be taking that same approach.

Hence, we generally find the draft rules to be a very solid effort in the initial attempt to craft appropriate program rules.

The leadership of our association has reviewed the draft in concert with our attorney, Lisa Hauser of the firm Gammage and Burnham and who also drafted the language of the Arizona Medical Marijuana Act. We respectfully offer our comments and suggestions regarding the draft rules which we believe will preserve the commitment of both DHS and our association to high industry standards, yet do not impose unreasonable and unnecessary regulations that result in the unintended consequences of increased cost to dispensaries and the patients they serve, simply driving patients back to the criminal market

We look forward to continuing engagement in the rule making process, the submission of additional comments and recommendations, and the ultimate adoption of rules consistent with the initiative approved by Arizona voters.

Thank you for your consideration, and for your service to our great state.

Respectfully,

Andrew Myers
Executive Director

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January 7, 2011

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Will Humble, Director
Arizona Department of Health Services
150 North 18th Avenue
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Re: ADHS Informal Draft Rules for Implementation of the Arizona Medical Marijuana Act; Comment by the Arizona Medical Marijuana Association

Dear Director Humble:

This constitutes the Arizona Medical Marijuana Association's ("AzMMA" or "Association") comments on the Arizona Department of Health Services' ("ADHS" or "Department") Informal Draft Rules for implementation of the Arizona Medical Marijuana Act. The Association is a non-profit, professional business organization created after the passage of Proposition 203. The Association's membership includes the individuals who, as the Arizona Marijuana Policy Project, qualified this measure for the ballot and then secured its passage. The Association's undersigned counsel authored the text of Proposition 203. The Association essentially is the successor of the Arizona Marijuana Policy Project. Thus, the Association is committed to the Act's implementation in a manner that furthers legislative intent.

The Association commends the Department for producing an initial set of draft rules so soon after the Act's effective date and for the inclusion of many prospective rules designed to ensure that Arizona serves as a national model for a well-regulated medical marijuana program that exists to serve the needs of patients with debilitating medical conditions. But the Association has serious concerns about whether a number of provisions, even if well-intentioned, are contrary to the intent of the Act. Some of the proposed regulations are invalid as impermissibly limiting the Act. Others exceed the Act's grant of authority to the Department and are inconsistent with or in conflict with the Act. In commenting on the proposed rules, the Association will endeavor to highlight those provisions that it applauds as well as those that give it concern.

Although the Association has reviewed the initial draft rules and offers its comments below, it has not commented on every aspect of the initial draft rules. The Association's failure to comment on

specific provisions is not intended to signify its agreement with those provisions. The Association expects to continue studying the proposed rules and expressly reserves the right to make future, additional comments about any rules contained in the Department's initial draft.

Rulemaking Authority

The Department's rulemaking authority is found in A.R.S. § 36-2803(A). The Department was not given the broad authority to "adopt rules necessary to carry out this chapter." Rather, it is authorized only "to adopt the rules set forth in subsection A." Permissible rules are those:

1. Governing the manner of adding to the list of debilitating medical conditions;

2. Establishing the form and content of registration and renewal applications;

3 Governing the manner in which it shall consider applications for and renewals of registry identification cards;

4 Governing nonprofit medical marijuana dispensaries—for the purpose of protecting against diversion and theft without imposing an undue burden on nonprofit medical marijuana dispensaries or compromising the confidentiality of cardholders—including:

(a) The manner in which the department shall consider applications for and renewals of registration certificates;[1]

(b) Minimum oversight requirements for dispensaries;

(c) Minimum recordkeeping requirements for dispensaries;

(d) Minimum security requirements for dispensaries, including requirements for protection of each registered nonprofit medical marijuana dispensary location by a fully operational security alarm system;

(e) Procedures for suspending or revoking the registration certificate of dispensaries that violate the Act or rules adopted pursuant to the Act; and

5 Establishing registration and renewal fees

[1] No rules were provided in this initial draft with respect to how the Department intends to evaluate dispensary applications. It is critical for these rules to be included in the next draft and made available for public comment.

All other rules are outside the scope of the Department's rulemaking power. Each initial draft rule should be closely examined by the Department to ensure that it is authorized pursuant to A.R.S. § 36-2803(A).

The 70% Cultivation Rule

The 70% production provision contained in proposed R9-17-307(C) appears to be drawn from the Colorado legislation (House Bill 1284) passed in May 2010. It requires that every medical marijuana center "must certify that it is producing at least 70% of its own medicine." This and other amendments were intended to bring better governance to an insufficiently controlled cultivation environment that resulted from shortcomings in the original Colorado medical marijuana law. Since the Arizona Act provides for strict controls for all medical marijuana cultivation in the state, this restriction is unnecessary and may, in fact, be bad public policy for Arizona.

The Act requires the establishment of at least 124 dispensaries in the State. It does not necessarily require the creation of at least 124 cultivation facilities, unless the proposed subsection R9-17-307(C) is enacted. It can be argued that fewer, larger, cultivation facilities decrease the potential for public nuisance, reduce ADHS oversight requirements and costs, increase security, and provide economies of scale that can reduce patient costs. Establishing an unimpeded market where any registered dispensary can choose to order its usable marijuana from any other registered cultivation facility will likely result in the greatest economic efficiencies and best prices for patients.

Many medical professionals or other entities that would otherwise be motivated and highly qualified to operate a dispensary may be deterred due to the technical, financial and liability issues associated with operating a cultivation facility. Under the Act, every registered dispensary has the right to operate a cultivation facility to meet the needs of its qualified patients. However, nothing in the Act precludes a stand-alone dispensary from arranging to obtain its usable marijuana from the cultivation facilities of one or more other dispensaries. Creating a regulatory environment that allows cooperative interaction between registered dispensaries and their associated cultivation facilities will structure an Arizona medical marijuana industry that rewards efficiency; with the foreseeable result of better-managed dispensaries and fewer, more efficient, cultivation facilities.

A proposed regulatory environment that allows commercial cooperation between registered dispensaries can be readily managed through rules that require cultivation facilities to establish procedures for verifying that a dispensary placing a order for usable marijuana has a registration certificate in good standing, that the usable marijuana is delivered in a secure manner, and that all orders are labeled, packaged, tracked and accounted for in a manner that prevents diversion.

The Department has the authority to adopt rules governing nonprofit medical marijuana dispensaries, for the purpose of protecting against diversion and theft without imposing an undue burden on dispensaries or compromising the confidentiality of cardholders, including minimum oversight requirements for dispensaries. Requiring each dispensary to cultivate at least 70% of the medical

marijuana it dispenses does not serve the purpose of protecting against diversion and theft and imposes an undue burden on dispensaries. More importantly, in A.R.S. § 36-2816(B) and (C), the Act specifically prohibits a dispensary from dispensing to or acquiring marijuana from any person other than another registered dispensary, a registered qualifying patient or a registered designated caregiver. Had the Act intended to limit transfers between dispensaries, it would have said so. Thus, the proposed rule is in conflict with the Act.

If the Department believes a rule is necessary in addition to A.R.S. § 36-2816(B) and (C), the Association suggests the following:

R9-17-307. Administration

C. A dispensary:

~~1. Shall cultivate at least 70% of the medical marijuana the dispensary provides to qualifying patients or designated caregivers;~~

~~2.~~1. ~~Shall~~ MAY only provide medical marijuana cultivated or acquired by the ~~dispensary~~ to another dispensary in Arizona, a qualifying patient or a designated caregiver authorized by A.R.S. Title 36, Chapter 28.1 and this Chapter to acquire medical marijuana.

~~3.~~2 May only acquire medical marijuana from another dispensary in Arizona, a ~~qualifying~~ patient, or a designated caregiver.

~~4. May acquire up to 30% of the medical marijuana the dispensary provides to qualifying patients and designated caregivers from another dispensary in Arizona, a qualifying patient, or a designated caregiver; and~~

~~5. Shall not provide more than 30% of the medical marijuana cultivated by the dispensary to other dispensaries.~~

The Physician/Patient Relationship

The Association believes that the existence of a legitimate physician/patient relationship is contemplated by the Act's requirement that a qualifying patient be diagnosed by a physician as having a debilitating medical condition and that the physician provide a written certification that, in his professional opinion, "the patient is likely to receive therapeutic or palliative benefit from the medical use of marijuana to treat or alleviate the patient's debilitating medical condition or symptoms associated with the debilitating medical condition" after the physician has completed a full assessment of the qualifying patient's medical history.

The Department's rulemaking authority set forth in A.R.S. § 36-2803 of the Act does not include adopting rules concerning the physician/patient relationship. A.R.S. § 36-2803(A)(3) provides that ADHS shall adopt rules "establishing the form and content of registration and renewal applications submitted under this chapter." But—unlike the authority granted with respect to the consideration of dispensary registration certificates—the statute does not grant ADHS the authority to adopt rules for the consideration of patient applications for registration cards. Accordingly, the Department is not authorized to add substantive requirements to the content of a qualifying patient's application or renewal beyond those set forth in the Act.

A.R.S. § 36-2804.02 requires that a qualifying patient applying for a registration card submit (1) the physician's written certification, (2) the application fee, and (3) the application. A.R.S. § 36-2801(18) specifies the content of the written certification. Although the physician's written certification must accompany the patient's applicant, it is separate from the application itself and the Department does not have the rulemaking authority to specify its content.

In the case of proposed R9-17-202(F)(5), the patient would be required to provide far more information than contemplated by A.R.S. § 36-2804.02, particularly with respect to the physician's written certification. Although proposed R9-17-202(F)(5)(e)(i), (ii) requires the physician to state the nature of his relationship with the patient in the alternative, both (i) and (ii) are objectionable as overly burdensome to the patients who are the Act's intended beneficiaries by dramatically impacting patient access. Consider this example. A patient diagnosed with cancer is referred to an oncologist. That patient's reaction to the chemotherapy administered by the oncologist involves such severe nausea that the patient's overall strength is severely diminished and his overall health and ability to withstand additional treatment is further compromised. The oncologist has only been treating the patient for a matter of weeks but is willing to write a recommendation for the patient's use of medical marijuana. Under this scenario, the physician could not make the statement required by R9-17-202(F)(5)(e)(i) *and* might have serious difficulty making the alternative statement required by R9-17-202(F)(e)(ii).

Notwithstanding any assertions the Department may make concerning the wisdom or substantive merit of these additional proposed physician certifications, the Association's position is that they are not authorized by the Act and would unlawfully require certifications beyond what the Act has mandated.

Time-Frames

The Act sets forth a number of time deadlines for the Department to perform various tasks. For example, A.R.S. § 36-2804 provides that the Department shall register a dispensary and issue a registration certificate "not later than ninety days" after receiving a dispensary application if the dispensary applicant has submitted certain specified items. The Association wholeheartedly supports the Department's proposal to ensure that the statutory time period does not begin to run until the application is complete as well as the proposals to give the Department a limited period of time to review applications for completeness and to give the applicant a period of time to provide missing information. But the Association's position is that a dispensary's registration certificate must be issued

not later than ninety calendar days from the date on which the Department has a completed application. The Department's proposed rules change the statutory time periods to "working days," significantly lengthen the time periods and are in conflict with the statute. This issue exists with respect to all statutory time periods set forth in Table 1.1.

In addition to the aforementioned problems with the time-frames listed in Table 1.1, there are numerous errors in Table 1.1 with respect to the "statutory authority" citations. These citations should be corrected in the next draft.

Outdoor Cultivation

The Association commends the Department for including provisions related to outdoor cultivation. But the proposed definition of "enclosed" in draft R9-17-101(10) requires one or another cumbersome barrier covering the top area. The association proposes the following amendment:

10. "Enclosed" means EITHER:

a. A building with four walls and a roof or an indoor room or closet.

b. An area surrounded by four solid 12-foot walls constructed of metal, concrete, or stone with a one-inch thick metal gate and a barrier covering the top of the area that is:

i. Welded or woven wire mesh, with minimum wire thickness of 0.25 inches and maximum gap between wires of 1 inch;

ii. Welded metal wire grid, with minimum wire thickness of 0.25 inches and maximum gap between wires of 3 inches;

iii. Metal chain-link weave, with gauge no less than 9 and no more than 11.5;

iv. A panel of metal vertical bars, with minimum bar thickness of 0.5 inches and maximum gap between bars of 4 inches; or

v. Constructed of iron or other metallic material and similar to the examples in subsections (10)(b)(i) through (10)(b)(iv), if approved by the Department.

c. AN AREA SURROUNDED BY FOUR SOLID 12-FOOT WALLS, TOPPED WITH CONCERTINA WIRE, CONSTRUCTED OF METAL, CONCRETE, OR STONE WITH A ONE-INCH THICK METAL GATE AND WITH 24-HOUR VIDEO SURVEILLANCE OF THE ENTIRE OUTER PERIMETER.

Inventory Controls

To more effectively inventory and track all usable marijuana, the AzMMA respectfully suggests that the ADHS augment its proposed "strain" and "registry identification" system with a "Batch" designator. Under this proposal, a "Batch" is simply one or more seeds or cuttings that are planted and harvested at the same time at a given cultivation site. Each Batch would be assigned a unique "Batch Number" by the dispensary operating the cultivation site. The cultivation site would also record:

1. Whether the Batch originated from seeds or cuttings;

2. The origin and strain of the seeds or cuttings;

3 The number of seeds or cuttings planted;

4. The date the seeds or cuttings were planted;

5 A list of all chemical additives, including non-organic pesticides, herbicides, and fertilizers, used in the cultivation and production of the medical marijuana;

6 The number and disposition of any male, failed, or otherwise unusable plants;

7. The number of female plants grown to maturity;

8 The harvest date of the mature female plants; and

9 The final processed usable marijuana yield weight of the Batch.

The AzMMA also believes that regulations R9-17-313, and R9-17-314 may benefit from making certain differentiations between inventory controls and labeling requirements for dispensaries and those requirements for cultivation sites. Accordingly, the Association submits the following proposed changes to the Department's initial draft regulations:

R9-17-101. Definitions:

Add the following definitions and renumber accordingly:

4. "BATCH" MEANS A SPECIFIC LOT OF MEDICAL MARIJUANA GROWN FROM ONE OR MORE SEEDS OR CUTTINGS THAT ARE PLANTED AND HARVESTED AT THE SAME TIME AT A CULTIVATION SITE.

5. "BATCH NUMBER" MEANS A UNIQUE NUMERIC, OR ALPHA-NUMERIC, DESIGNATOR ASSIGNED TO A BATCH BY A DISPENSARY AT ITS CULTIVATION SITE

R9-17-313. Inventory Control System

A. A dispensary shall designate in writing a dispensary agent who has oversight of the dispensary's medical marijuana inventory control system.

B. A dispensary shall establish and implement an inventory control system for the ~~dispensary's medical~~ USABLE marijuana LOCATED AT THE DISPENSARY that documents:

1. Each day's beginning inventory, acquisitions, ~~harvests,~~ sales, disbursements, ~~disposal of unusable marijuana,~~ and ending inventory BY AMOUNT, BATCH NUMBER AND REGISTRY NUMBER;

2. For acquiring medical marijuana from ~~a qualifying patient, designated caregiver, or~~ another dispensary OR CULTIVATION SITE:

   a. A description of the medical marijuana acquired including the amount and ~~strain~~ BATCH NUMBER;

   b. The name and registry identification number of the ~~qualifying patient, designated~~ caregiver~~, or~~ dispensary and dispensary agent who provided the medical marijuana;

   c. The name and registry identification number of the dispensary agent receiving the medical marijuana on behalf of the dispensary; and

   d. The date of acquisition~~;~~.

~~3. For cultivation:~~

   ~~a. The strain of~~ marijuana ~~seed planted, type of soil used, date seeds were planted, and the watering schedule;~~

   ~~b. Harvest~~ information ~~including:~~

      ~~i. Date of harvest;~~

      ~~ii. Amount of medical marijuana harvested, including the amount of marijuana and the amount of usable marijuana;~~

      ~~iii. Name and registry identification number of the dispensary agent responsible for the harvest; and~~

~~e. The disposal of~~ medical ~~marijuana that is not usable marijuana including the:~~

~~i. Date of disposal,~~

~~ii. Method of disposal, and~~

~~iii. Name and registry identification number of the dispensary agent responsible for the disposal;~~

3. FOR ACQUIRING MEDICAL MARIJUANA FROM A QUALIFYING PATIENT OR DESIGNATED CAREGIVER:

a. A DESCRIPTION OF THE MEDICAL MARIJUANA ACQUIRED INCLUDING THE AMOUNT AND STRAIN;

b. THE NAME AND REGISTRY IDENTIFICATION NUMBER OF THE QUALIFYING PATIENT OR DESIGNATED CAREGIVER WHO PROVIDED THE MEDICAL MARIJUANA; AND

c THE DATE OF ACQUISITION.

4 For providing medical marijuana to another dispensary:

a. The amount and ~~strain~~ BATCH NUMBER of THE medical marijuana provided~~;~~;

b. The name and registry identification number of the other dispensary~~;~~;

c. The name and registry identification number of the dispensary agent who received the medical marijuana on behalf of the other dispensary~~;~~; and

d. The date the medical marijuana was provided~~;~~.

5. For providing medical marijuana to a food establishment for infusion into an edible food product:

a. A description of the medical marijuana provided including the amount and ~~strain~~ BATCH NUMBER;

b. The name and registry identification number of the designated agent who:

i. Provided the medical marijuana to the food establishment on behalf of the dispensary, and

ii. Received the medical marijuana on behalf of the food establishment~~; and~~.

c. The date the medical marijuana was provided to the food establishment~~; and~~.

6. For receiving edible food products infused with medical marijuana from a food establishment:

a. The date the medical marijuana used to infuse the edible food products was received by the food establishment and the amount AND BATCH NUMBER of THE medical marijuana received;

b. A description of the edible food products received from the food establishment, including total weight of each edible food product and estimated amount AND BATCH NUMBER of THE medical marijuana infused in each edible food product;

c Total estimated amount AND BATCH NUMBER of THE medical marijuana infused in edible food products;

d. A description of any reduction in the amount of medical marijuana;

e. For any unusable marijuana disposed of at the food establishment:

i. A description of the unusable marijuana,

ii. The amount AND BATCH NUMBER of THE unusable marijuana disposed of,

iii. Date of disposal,

iv. Method of disposal, and

v Name and registry identification number of the dispensary agent responsible for the disposal at the food establishment~~; and~~

f The name and registry identification number of the designated agent who:

i. Provided the edible food products to the dispensary on behalf of the food establishment, and

ii. Received the edible food products on behalf of the dispensary.

g. The date the edible food products were provided to the dispensary.

C. A DISPENSARY CULTIVATION SITE SHALL ESTABLISH AND IMPLEMENT AN INVENTORY CONTROL SYSTEM THAT DOCUMENTS:

1. EACH DAY'S BEGINNING INVENTORY, DELIVERIES, AND ENDING INVENTORY BY BATCH NUMBER, INCLUDING WHETHER EACH BATCH ON HAND IS IN CULTIVATION, IN PROCESSING, OR STORED AS PROCESSED USABLE MARIJUANA;

2. THE AMOUNT AND BATCH NUMBER OF ALL PROCESSED USABLE MARIJUANA STORED OR OTHERWISE LOCATED AT THE CULTIVATION SITE;

3. FOR MEDICAL MARIJUANA PROVIDED TO ANOTHER DISPENSARY:

A. THE AMOUNT AND BATCH NUMBER OF THE MEDICAL MARIJUANA PROVIDED;

B. THE NAME AND REGISTRY IDENTIFICATION NUMBER OF THE OTHER DISPENSARY;

C. THE NAME AND REGISTRY IDENTIFICATION NUMBER OF THE DISPENSARY AGENT WHO RECEIVED THE MEDICAL MARIJUANA ON BEHALF OF THE OTHER DISPENSARY; AND

D. THE DATE THE MEDICAL MARIJUANA WAS PROVIDED.

4. FOR MEDICAL MARIJUANA PROVIDED TO A FOOD ESTABLISHMENT FOR INFUSION INTO AN EDIBLE FOOD PRODUCT:

A. A DESCRIPTION OF THE MEDICAL MARIJUANA PROVIDED INCLUDING THE AMOUNT AND BATCH NUMBER; AND

B. THE DATE THE MEDICAL MARIJUANA WAS PROVIDED TO THE FOOD ESTABLISHMENT.

5. HARVEST INFORMATION INCLUDING:

A. DATE OF HARVEST FOR EACH BATCH;

B. AMOUNT OF MEDICAL MARIJUANA HARVESTED IN EACH BATCH, INCLUDING THE AMOUNT OF USABLE MARIJUANA AND THE AMOUNT OF NOT USABLE MARIJUANA;

C. THE DISPOSAL OF MEDICAL MARIJUANA THAT IS NOT USABLE MARIJUANA INCLUDING THE:

I. BATCH NUMBER AND AMOUNT;

II. DATE OF DISPOSAL; AND

III. METHOD OF DISPOSAL.

~~C~~D. The individual designated in subsection (A) shall conduct and document an audit of the dispensary's inventory according to generally accepted accounting principles at least once every 30 calendar days.

1. If the audit identifies a reduction in the amount of medical marijuana in the dispensary's inventory not due to documented causes, the dispensary shall determine where the loss has occurred and take and document corrective action.

2. If the reduction in the amount of medical marijuana in the dispensary's inventory is due to suspected criminal activity by a dispensary agent, the dispensary shall report the dispensary agent to the Department and to the local law enforcement authorities.

~~D~~E. A dispensary shall:

1. Maintain the documentation required in subsections (B) and (C) at the dispensary for five years from the date on the document, and

2. Provide the documentation required in subsections (B) and (C) to the Department for review upon request.

R9-17-314. Product Labeling and Analysis

A. A dispensary shall ensure that medical marijuana provided by the dispensary to a qualifying patient or a designated caregiver is labeled with:

1. The dispensary's registry identification number;

2. The amount, BATCH NUMBER and strain of medical marijuana;

3. If not cultivated by the dispensary, whether the medical marijuana was obtained from a qualifying patient, a designated caregiver, or another dispensary;

4. The date of manufacture, harvest, or sale;

5. A list of all chemical additives, including ~~nonorganic~~ NON-ORGANIC pesticides, herbicides, and fertilizers, used in the cultivation and production of the medical marijuana; and

6. The registry identification number of the qualifying patient.

B A DISPENSARY CULTIVATION SITE SHALL ENSURE THAT EACH PACKAGE OF MEDICAL MARIJUANA PROVIDED BY THE CULTIVATION SITE TO A DISPENSARY IS LABELED WITH:

1. THE DISPENSARY CULTIVATION SITE'S REGISTRY IDENTIFICATION NUMBER;

2. THE AMOUNT, BATCH NUMBER AND STRAIN OF THE MEDICAL MARIJUANA;

3. THE DATE OF MANUFACTURE, HARVEST, OR SALE; AND

4. A LIST OF ALL CHEMICAL ADDITIVES, INCLUDING NON-ORGANIC PESTICIDES, HERBICIDES, AND FERTILIZERS, USED IN THE CULTIVATION AND PRODUCTION OF THE MEDICAL MARIJUANA.

~~B~~C. If medical marijuana is provided as part of an edible food product, a dispensary, shall, in addition to the information in subsection (A), include on the label:

1 The total weight of the edible food product; and

2. The following statement "This product is infused with medical marijuana and was produced without regulatory oversight for health, safety, or efficacy. There may be health risks associated with the consumption of the product."

~~C~~D A dispensary shall provide to the Department upon request a sample of the dispensary's medical marijuana inventory of sufficient quantity to enable the Department to conduct an analysis of the medical marijuana.

Certificate of Occupancy

Proposed R9-17-302 sets forth the contents of the application for a dispensary certification. One of those requirements is "[a] copy of the certificate of occupancy or other documentation issued by the

local jurisdiction to the applicant authorizing occupancy of the building as a dispensary[2] and, if applicable, as the dispensary's cultivation site." R9-17-302(B)(5). This imposes an undue burden on dispensaries to make the major capital investments necessary in order to prepare a site for occupancy as a dispensary or cultivation site without any assurance that certification will be granted. Although the Department has the authority to adopt rules governing nonprofit medical marijuana dispensaries for the purpose of protecting against diversion and theft, those rules cannot impose "an undue burden on nonprofit medical marijuana dispensaries." A.R.S. § 36-2803(A)(4). Requiring a certificate of occupancy to be issued to a proposed dispensary before it even has preliminary approval from the Department is also an undue burden on counties and municipalities.

In contrast, the Department's proposed R9-17-107 contemplates that an application may be completed over time and that the Department may issue a preliminary approval of the dispensary registration certificate and identification number pending approval of at least one principal officer or board member as a dispensary agent. The Association welcomes this sort of tiered approach to the application process and suggests that the requirement for producing a certificate of occupancy be moved to a later stage by delaying the final approval or effective date of the certification until the appropriate certificates of occupancy have been issued.

Audits

Proposed R9-17-305(2) and (3) requires that a dispensary applying for renewal must provide a copy of an audited financial statement for the previous year. Because a registration certificate is effective for only one year and the renewal application must be made 30 days prior to expiration, it will be impossible to provided a full, annual financial statement. This requirement needs to be revisited and revised so that it is not internally inconsistent.

The Association fully supports requiring dispensaries to provide the financial information necessary to determine that it is operating as a nonprofit and that funds are not being diverted, etc. But an audited financial statement seems to exceed what it necessary and the cost would be unduly burdensome to entities required to operate as non-profits. The Association suggests that the Department consider other alternatives. For example, a compilation as well as copies of the entity's tax returns may provide the information the Department needs in a less burdensome way.

Medical Director

The Association sees value to a dispensary affiliation with a Medical Director, but suggests that it is more consistent with the scope of the Department's rulemaking authority to use the existence of a Medical Director as an evaluation criterion rather than as a mandatory requirement for all dispensaries

[2] It is also unclear whether a certificate of occupancy can or will be issued by a jurisdiction for a particular purpose such as this.

Proposed R9-17-101(15) defines a Medical Director in such a way that all Medical Directors must be medical doctors or osteopaths even though the Act allows medical doctors, osteopaths, naturopaths and homeopaths to certify a patient for the medical use of marijuana. In addition, R9-17-310 limits a Medical Director to serving only three dispensaries at any time. Together, these provisions may make it extremely difficult for dispensaries to operate in Arizona's rural counties. The Department should state its rationale for these provisions so that the public can evaluate whether they impermissibly limit the Act.

Security Requirements

The Association supports strong security requirements and believes that they are not only good public policy but further the purpose of the Act. However, the Association is concerned that the requirement, in proposed R9-17-306, that a dispensary provide the Department with authorized remote access to the dispensary's electronic monitoring system is problematic. If the Department wants a live feed, there must be very strong encryption to protect patient confidentiality. The system requirements for a live feed may be unduly burdensome for dispensaries. Other alternatives should be considered such as requiring a minimum of 30-days storage of the electronic monitoring system images.

Transportation Requirements

The Department's initial draft rules contain no provisions relative to the transportation of medical marijuana between dispensaries, cultivation sites, patients, etc. The Association believes such rules are necessary and appropriate for the Department to promulgate. Some suggestions in this regard are that:

- Vehicles used for delivery not bear any identifying markings.
- The dispensary must maintain current commercial motor vehicle insurance as required by Arizona law.
- Only registered dispensary agents with access to a form of secure communication with the dispensary may staff any vehicle during the delivery of usable marijuana.
- All usable marijuana be transported in a locked container that is locked in the trunk or otherwise secured within the vehicle used to transport the marijuana.

Pharmacist / Surety Bond Information

Proposed R9-17-302 sets forth the contents of a dispensary application. R9-17-302(B)(15) proposes to ask whether "[a] registered pharmacist will be onsite or on-call during regular business hours" and "[w]hether the dispensary has a surety bond and, if so, how much." The Association is

unclear as to whether the Department seeks to require these items or whether they will be used as evaluation criteria. If intended to be a requirement, the pharmacist provision is extremely problematic and unduly burdensome for dispensaries. And the reference to a surety bond, generally required to guarantee performance of a legal obligation, does not appear to make any sense in this context. In short, some further explanation from the Department is necessary to permit informed comment.

Notice of Inspection

A.R.S. § 38-3806(H) provides that medical marijuana dispensaries are subject to reasonable inspection by the Department and that the "Department shall give reasonable notice of an inspection under this subsection." Proposed R9-17-306 goes beyond defining "reasonable notice of an inspection."

Proposed R9-17-306(A) provides that the submission of an application constitutes permission for entry to and inspection of the dispensary. It does not reference any "reasonable notice requirement" and does not limit this inspection to the inspection associated with the Department's review of a dispensary application (proposed R9-17-306(C) provides for 5 working days notice of a certification or compliance inspection). The application of the 5-day notice to the inspection referenced in (A) needs to be clarified. If the notice provision is intended to apply, it may be advisable to combine (A) and (C).

Proposed R9-17-306(E) allows an *unannounced* inspection of a dispensary or cultivation site based on "an allegation" of noncompliance with the Act or Department rules. This is contrary to the express intent of the Act that Department inspections be conducted upon reasonable notice. If the Department receives information of a possible criminal violation of the Act or other laws, it should refer those to the appropriate law enforcement agency for follow-up. The proper method of entering without notice under those circumstances is for the law enforcement agency to establish probable cause to believe that a crime has been or is being committed and to secure a search warrant. The Act does not preclude the appropriate investigation of criminal offenses, but it absolutely protects dispensaries from Department inspections without notice. Subsection (E) of this proposed rule should be eliminated.

Cleaning Requirements

With respect to proposed R9-17-317(A)(1), the Association suggests that the word "securely" be deleted and replaced with "reasonably." This change is suggested because, if this provision is intended to apply to outdoor cultivation, it is impossible to protect plants from dust, for example.

Residency Requirement

The Association is very supportive of the residency requirement for principal officers and board members of dispensaries contained in the initial draft rules and suggests that the requirement be strengthened from two to three years and that these applicants be required to furnish three years of Arizona tax returns to the Department for additional proof of residency only.

It is important that dispensary officials have sufficient ties to Arizona. This new industry must be protected from those who would undermine it and undermine public confidence in the ability to have a legitimate medical marijuana program. Those with strong Arizona ties will have a greater incentive to ensure the program's long-term success. Also, Arizona residents are more easily subject to the state's jurisdiction in the event of a problem. The Association wants Arizona to avoid the mistakes made by other states. A residency requirement helps to prevent those that created problems in other states from bringing the same set of problems to Arizona.

CONCLUSION

Again, the Association commends the Department for its efforts in creating the initial draft rules. It hopes that the foregoing comments and suggestions will be of assistance to the Department as it prepares the next draft. In the interim, the Association is available to discuss any portion of this rule comment or to answer any questions you may have. Please let us know if we can be of assistance.

Sincerely,

GAMMAGE & BURNHAM

By Lisa T. Hauser

Lisa T. Hauser

LH/dmm

The Law Office of

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January 7, 2011

Via facsimile to 602-542-1062
Original to follow via U.S. Mail

RECEIVED
11 JAN 10 PM 1:45
ADHS
DIRECTORS OFFICE

Will Humble, Director
Arizona Dept. of Health Services
150 N. 18th Ave., Suite 500
Phoenix, AZ 85007-3247

RE: 12/17/10 Draft Rules for Arizona Medical Marijuana Program

Dear Mr. Humble:

I am writing this letter on behalf of a client who intends to provide information and services for patients in connection with the Arizona Medical Marijuana Program. We have thoroughly reviewed the text of Prop 203, as well as the 12/17/10 Draft Rules (the "Draft Rules"). The following are my comments and suggestions.

Overall, the Draft Rules do not appear to place the interests of Arizona at the forefront. In their current draft form, the rules are designed to benefit a few wealthy individuals, and they essentially lock out smaller Arizona entrepreneurs from competition and access to opportunities to make Arizona's Medical Marijuana Program a model for future state programs. The current rules stifle competition and would create a de facto monopoly by artificially locking the wholesale to the retail business with the 70/30 requirement proposed under DR9-17-307, which has no basis in Prop 203. This will not only stifle competition, but will also result in artificially inflated prices for medical marijuana. The effect will be that few licensees will benefit, and patients and caregivers in outerlying areas will suffer. This artificial cost structure will no doubt negatively impact the industry in the long term.

What is very troubling about the rules is how they propose to establish guidelines for issuing dispensary licenses. In its current form, the rules require an applicant to possess a certificate of occupancy or some other documentation issued by a local authority authorizing occupancy as a condition for obtaining a dispensary license. DR R9-17-302(B)(5). The applicant must also submit site plans and floor plans for the dispensary and the cultivation site to be eligible. DR R9-17-302(B)(8 - 11). This rule favors those few who have the financial wherewithal to (a) locate a site that complies with local zoning laws, (b) prepare and submit site and floor plans to obtain a building permit, (c) construct the facilities, (d) pass inspections, and (e) obtain a certificate of occupancy.

All of this must be accomplished *before* an application can be considered. These requirements are an undue burden, are arbitrary and capricious, and they are not supported by the language of Prop 203

The proposed rules appear to be cut from whole cloth with no basis in the law and without consideration for the fairness of the licensing process. Such regulations are undoubtedly subject to challenge in the courts and possible disruption of implementation of the program by injunctive relief. Perhaps granting a provisional license to an otherwise qualified applicant pending zoning approval and obtaining a certificate of occupancy will level the playing field. Putting the cart before the horse only benefits those with enough horse power to push the cart

In addition, the licensing procedure should be less subjective and more transparent. Allowing licenses to be issued by using subjective criteria promotes all that is bad about politics and business in America: cronyism, graft, illegal contributions, corruption, etc. Instead, licenses should be granted by way of a lottery or auction. All pre-qualified candidates should have an equal chance at obtaining a license. Licenses should not be awarded solely to those who have the most money or who can afford to meet the current requirements and suffer the consequences without much harm if a license is not awarded to them.

Regarding the non-profit status of entities described in §36-2806 of Prop 203, the following questions should be answered to provide guidance to dispensaries and to prohibit abuses:

- Can a license owner sell a dispensary license for a profit?
- How much can a dispensary retain above its short term needs?
- How much can dispensary management be compensated?
- What related-party transaction protections will be implemented?
- What accounting information must a dispensary share (and with whom and how often) to demonstrate its non-profit status?
- What rights will the public have to question the non-profit status of a dispensary that is not required to be recognized as tax-exempt by the IRS under §36-2806(A)?

Failure to address these issues will not only result in abuse of the system, it will also result in the perception that the ADHS tacitly approves weak controls to allow the powerful few to exploit the system and turn a huge profit in violation of Prop 203

With respect to the Medical Director requirement proposed in DR R9-17-310, please explain how ADHS has authority to mandate such a requirement given the fact that the need for a medical director apparently has no basis in Prop 203. Undoubtedly, implementation of this provision would be costly to dispensaries, and ultimately to patients down the stream of commerce. Doctors' salaries, malpractice insurance, and other associated costs will have to be absorbed by dispensaries on a pro

rata basis. This provision appears to be poorly conceived to employ lots of doctors who have little or no knowledge of the subject matter, and it raises the question whether doctors were involved in the drafting of these rules to provide doctors with a retirement pension, so to speak.

In the interests of patients, the ADHS should instead employ an industry-supported medical director to be headquartered at ADHS to help oversee and administer the program. The medical director's salary should be paid from revenues generated pursuant to §36-2803(A)(5).

Finally, the Draft Rules are silent as to the acquisition of initial strains of medical marijuana and the addition of new strains as time progresses. Dispensaries need a legal method for obtaining genetic strains of medical marijuana, and this issue needs to be addressed in the context of current federal laws. Failure to address it will result in dispensaries technically having to violate the law to conduct business. For instance, from where will seeds and plants be acquired? Will interstate commerce be infringed by prohibiting the acquisition of seeds and/or plants from states that currently allow the use of medical marijuana? These are just a few of the many questions that go unanswered but need to be addressed. Perhaps the following language could be considered in any future rules:

> "Dispensaries shall be allowed to obtain seeds and/or marijuana plants for the purpose of perpetuating specific genetics during the calendar year 2011. After 2011, any dispensary can petition the ADHS Director for approval to obtain additional seeds and/or marijuana plants to add new genetics, and ADHS shall approve such petitions that provide for protection of the supply chain from theft and/or diversion."

I appreciate the opportunity to provide my feedback, and I would welcome a meeting with you and my client to discuss these issues and implementation of the program in general, including the review of future draft rules before they are proposed once again. If you have any questions, or if you wish to discuss any matters set forth herein, please do not hesitate to contact me. Thank you.

Sincerely,

Jeffery H. Hernandez

JJH:jh

cc: Tom Horne, Arizona Attorney General

LPL Financial

Ryan G Toronto, MBA
Investment Advisor Representative

1270 E Broadway Rd #112
Tempe, AZ 85282
480 966 3131 *office*
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[redacted]

January 6, 2011

Will Humble
Director, Arizona Department of Health Services
150 N. 18th Avenue, Suite 500
Phoenix, AZ 85007-3247

RE: Medical Directors of Medical Marijuana Dispensaries;
Allowing Registered Pharmacists as well as Medical Doctors

Director Humble:

I am submitting this letter due to what I believe is valuable input into the development of the Administrative Code for the Arizona Medical Marijuana Act.

I believe the proposal to require each medical marijuana dispensary to have a Medical Director that is a medical doctor (either an M.D. or a D.O.), will effectively put control of the entire industry in the hands of a few. While I see the need for Medical Directors, I believe Registered Pharmacists should also be allowed to act as Medical Directors for dispensaries. This will open up the pool of candidates that could potentially act as Medical Directors for dispensaries, thereby eliminating the potential monopoly doctors could have over the industry.

Forcing medical marijuana dispensaries to keep a doctor on staff would create an inflated expense for the business operations of the dispensaries and may affect their ability to compete. It may also create a situation where doctors are the only one's able to afford to run a dispensary, because they would not have to pay themselves (and incur the business expense). If doctors become entrenched as Medical Directors of dispensaries, they could control how much they charge dispensaries for their services and have an unfair impact over the business cost structure.

Pharmacists are regulated, licensed professionals in the field of healthcare and have expertise in counseling patients on how to use their medication. Let them be part of the solution, help keep costs down, and prevent a monopolization of the industry by doctors.

Furthermore, under current draft guidelines, acting Medical Directors for dispensaries would not be allowed to write medical marijuana recommendations, anyway. The patient would have to obtain their recommendation prior to coming to the dispensary. Therefore, doctors will still be part of the process; they just will not have an inequitable impact on the cost structure of dispensary operations. Doctors will still have the opportunity to evaluate symptoms, changes in symptoms, and the need to recommend medical marijuana during initial physician-patient consultations and follow up consultations.

LPL Financial

Ryan G. Toronto, MBA
Investment Advisor Representative

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This is being submitted by a concerned citizen and businessman, who is concerned with maintaining fair competition for all Arizonans that have a desire to become involved in this new industry.

I have worked as a Financial Advisor in the Valley for 17 years and am a graduate of the Thunderbird School of Global Management. I can be reached for further comment at (480) 966-3131.

Thank you for taking the time to review these suggestions.

Sincerely,

Ryan Toronto

Ryan G. Toronto, MBA
Financial Advisor

Stephanie Bishop

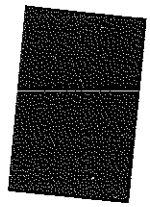
From: Sabrina Vazquez [sabrina@barnesaz com]
Sent: Thursday, January 06, 2011 9:28 AM
To: Stephanie Bishop
Cc: Thomas Salow
Subject: Letter to the Director from AzNMA

Tom Salow

Hello,

Below is a letter to Director Humble from the President of the Arizona Naturopathic Medical Association. Thank you for your time

Sabrina Vazquez
Barnes & Associates
331 N 1 Ave, Suite 101
Phoenix, AZ 85003
Phone: 602-452-2943
Cell: 602-503-8354
Fax: 602-452-2942



Arizona Department of Health Services
Office of the Director
150 North 18th Avenue
Phoenix, Arizona 85007

January 4, 2011

Dear Direct Humble,

The Arizona Naturopathic Medical Association (AzNMA) applauds the effort and dedication of the Arizona Department of Health Services to create a regulatory system that will allow for a responsible Medical Marijuana Program Thank you for the opportunity to comment on and participate in, the rules making process.

At this time AzNMA has three requests for changes to the rules as the process moves forward The requests are as follows:

1. The Naturopathic, Allopathic and Osteopathic Boards of Examiners should require physicians who recommend medical marijuana to complete no less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that covers the clinical, pharmacological, ethical and legal aspects of using medical marijuana in patient care

2. Naturopathic Physicians should be included in the definition of "medical director" as they are included in the definition of "physician" in the voter approved Medical Marijuana Act and authorized to recommend medical marijuana to qualifying patients. In this instance naturopathic physicians have the same qualifications as allopathic and osteopathic doctors to successfully serve as medical directors.

3. Patients with a terminal illness should be exempt from the rule requiring a patient to have a professional relationship with a physician for at least one year and assessed for their medical condition on at least four visits prior to being eligible for a medical marijuana recommendation.

AzNMA appreciates the department's attention to these matters and encourages the suggested changes be included in the formal draft rules released later this month.

We have contacted the department and discussed these issues with your rules attorney. Thank you for your time.

Sincerely,
Amy Terlisner N D
President of Arizona Naturopathic Medical Association

P.O. Box 18640 Tucson, AZ 85731-8640
Phone: (520) 298-4781

Arizona Department of Health Services
Office of the Director
WILL HUMBLE, DIRECTOR
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Phoenix, Arizona 85007-3247
(602) 542-1025
(602) 542-1062 FAX
Internet: www.azdhs.gov

[redacted]

Re: Official Comments on Arizona Proposition 203 Proposed Rules

January 5, 2011

The following was submitted to your office via your electronic form on January 5, 2011 at 0823 hours:

The interests of individual citizens who own firearms are of utmost concern. Therefore, the qualifying patient registry identification card must be eliminated as a requirement.

RATIONALE: It will remain illegal for an individual to possess and use marijuana under federal law (21 USC §811). In Gonzales v. Raich, 545 U.S. 1 (2005), the United States Supreme Court held that the federal government has the constitutional authority to prohibit marijuana for all purposes. In a 6-3 opinion delivered by Justice John Paul Stevens, the Court held that the commerce clause gave Congress authority to prohibit the local cultivation and use of marijuana, despite state law to the contrary.

Any individual who purchases a firearm from a federally licensed firearms (FFL) dealer must complete a BATFE Form 4473. Question 11e, which is a YES or NO question, reads as follows:

"Are you an unlawful user of, or addicted to, marijuana or any depressant, stimulant, narcotic drug, or any other controlled substance?"

This puts the potential purchaser of a firearm in a quandary. The individual purchaser can neither answer YES nor NO to BATFE Form 4473, question 11e because, 1) Lying on this form is a felony and can be punished by up to five years in prison in addition to fines and 2) Answering YES will result in a denial of purchase order from the National Instant Criminal Background Check System (NICS) This will effectively deny the individual right to keep and bear arms for anyone who submits an application for a Patient Registry Identification Card.

Furthermore, filing an application for the Patient Registry Identification Card will abridge those rights conferred in the United States Constitution, Articles in Amendment, Amendment 5, especially self-incrimination, among others.

Additionally, in order to prevent an occurrence in Arizona like what happened in Oregon, rules must be written and implemented that prohibit the declination of an Arizona Concealed Carry Weapons permit based solely on ones application and/or issuance of a Patient Registry Identification card and/or the purchase of medical marijuana from a dispensary.

Kenneth R. Rineer

Kenneth R. Rineer
President

KIND CLINICS
MEDICAL MARIJUANA DISPENSARIES

[redacted]

Date: January 6, 2011

Director Will Humble
Arizona Department of Health Services
150 N 18th Avenue
Phoenix, AZ 85007

Re: Comments Regarding Draft Rules on State Medical Marijuana Program

Dear Director Humble:

Kind Clinics is dedicated to helping establish the highest possible standards for the medical marijuana industry. We have experience in every state that currently allows medicinal use of marijuana. Kind Clinics is committed to helping develop the medical marijuana industry as a secure and well-regulated system that promotes ease of use for truly qualified patients and a level of comfort from the community and lawmakers that the system will be effective and secure

We appreciate the opportunity to make comments on the draft rules implementing the State Medical Marijuana Program. We want to assist in being the leader in implementing rules that will establish a secure, efficient, safe and fraud-proof system from seed to sale of medical marijuana. We are pleased to contribute to the process. Suggested language for the rules is in italics, with language to be removed indicated by a strikethrough.

I. THE RULES SHOULD ESTABLISH THE STANDARDS BY WHICH DHS WILL ASSESS DISPENSARY APPLICATIONS IF THE NUMBER OF APPLICATIONS EXCEEDS THE NUMBER OF REGISTRATION CERTIFICATES THAT THE DEPARTMENT MAY ISSUE.

The proposed rules should acknowledge that the number of dispensary registration certificates that the Department may issue is limited to one for every ten pharmacies registered and operating in Arizona. A.R.S. § 36-2804(C) Section R9-17-107(G) provides that DHS *shall* issue a dispensary registration certificate if DHS determines that the application is complete and the applicant complied with A.R.S. Title 36, Chapter 28.1 and the rules. The only two reasons listed for denial are that the applicant does not comply with A.R.S. Title 36, Chapter 28.1 and the rules or that the applicant has failed to submit information after DHS makes a request.

The rules need to acknowledge the limits in place on the number of dispensary registration certificates that the Department may issue The rules also need to address how the Department will decide to which dispensaries to issue registration certificates if the number of applications exceeds the number of permissible dispensaries

A. The Department Should Establish Time Frames for Accepting Applications.

Because the limit on the number of dispensary registration certificates is based on the number of pharmacies, it is possible that the number of pharmacies and dispensaries will increase. The Department needs to establish a procedure for announcing the availability of dispensary registration certificates and a window for accepting and reviewing applications, starting with the first set of applications that will be reviewed starting in April 2011

This time frame would work in conjunction with the selection criteria discussed in Section B below to help ensure that the Department timely receives and processes applications but is also able to select the best qualified

applicants that demonstrate the greatest likelihood of providing a safe, secure, efficient dispensary. The Department could add a new rule:

> *When dispensary registration certificates are available, the Department shall issue a notice identifying the number of dispensary registration certificates available and the deadline for applying for the dispensary registration certificates, which shall not be more than 21 calendar days after the date of the notice. All applications received during this period will be evaluated and weighed based on the criteria established in Section ___. When the number of dispensaries to which the Department has issued a dispensary registration certificate meets the number of dispensary registration certificates that are permitted by A.R.S. § 36-2804(C), the Department shall issue a notice that there are no dispensary registration certificates available.*

B. <u>The Department Should Establish Standards to Evaluate Applications.</u>

Maine and New Jersey also limit the number of dispensaries that may operate in their states. Each has created or proposed a system for evaluating and weighing applicants based on various factors. Each has a panel to select the applicants to whom dispensary licenses will be issued. We recommend that Arizona implement a similar system to help ensure that the dispensaries that receive registration certificates are the ones most likely to operate a professional, secure, fraud-proof dispensary. The system adopted in Maine uses a point system and any applicant with less than 70 points will not be considered, which may be beneficial in Arizona and save time for the Department.

We recommend adding a new rule that sets out factors that the Department will evaluate before issuing a dispensary registration certificate.

LIMITATION ON NUMBER OF DISPENSARIES AND SELECTION CRITERIA

A. Limitation on number of dispensaries. The Department may not issue more than one nonprofit medical marijuana dispensary registration certificate for every ten pharmacies that have registered under A.R.S. § 32-1929, have obtained a pharmacy permit from the Arizona Board of Pharmacy and operate within the State except that the Department may issue nonprofit medical marijuana dispensary registration certificates in excess of this limit if necessary to ensure that the Department issues at least one nonprofit medical marijuana dispensary registration certificate in each county in which an application has been approved.

B. Selection process. If the applications for a dispensary registration certificate exceed the number of dispensary registration certificates that may be issued, the Department shall convene a panel to evaluate and score each application using the criterion in subsection ___. To be considered for a dispensary registration certificate, an application must score at least 70 points. Subject to the limitations of the number of dispensaries, the Department shall issue a dispensary registration certificate to the applicants with the highest scores.

C. Selection criteria. Each complete application containing all of the information required in R9-17-302 shall be evaluated and scored based on:

1 Security & Inventory Control (50 points maximum). Factors to be considered include, but are not limited to:

- *the application demonstrates that the dispensary and cultivation facility, if applicable, will meet or exceed the standards established in these rules;*
- *the policies and procedures will discourage unlawful activity;*
- *the policies and procedures include a policy for identifying and reporting unlawful activity;*
- *the policies and procedures demonstrate that transportation of medical marijuana and paraphernalia will be conducted in a safe and secure manner that will minimize the likelihood of theft or loss;*
- *the likely effectiveness of methods and tools to prevent and reduce fraud and abuse.*

- *Up to 5 additional points should be awarded for exceeding the minimum standards established in these Rules.*

2. *Business plans and policies (25 points maximum) Factors to be considered include, but are not limited to:*

   - *the business plan demonstrates the ongoing viability of the dispensary as a non-profit organization, which may include a detailed description of the amount and source of the equity commitment and debt obligations for the dispensary that demonstrate the immediate and long-term financial feasibility of the proposed financing plan and the relative availability of funds for capital and operating needs;*

   - *the dispensary by-laws contain provisions for disposition of revenues and receipts to maintain non-profit status;*

   - *the patient record-keeping policies demonstrate that the patient information will be secure from access by or distribution to unauthorized parties; and*

   - *the plan for patient education and documentation of patient pain demonstrates an understanding of the benefits and risks of medical marijuana.*

3. *Other (25 points maximum). The panel may consider other factors, including but not limited to:*

   - *factors that demonstrate the likelihood that the dispensary will successfully operate in a safe, secure, and effective manner in compliance with all applicable laws and rules;*

   - *location of dispensary;*

   - *business experience;*

   - *industry expertise;*

   - *affiliation with other non-profit organizations;*

   - *commitment to and use of up-to-date technology;*

   - *commitment to community service;*

   - *application is timely submitted;*

   - *application is fully complete and does not require supplemental information; and*

   - *commitment to developing the industry in safe, secure, fraud-proof manner that keeps medical marijuana used for the purposes intended by A.R.S. Title 36, Chapter 28.1.*

C. <u>If the Department Does Not Adopt a Formal Evaluation System, It Should Still Consider the Most Qualified Applicants When Issuing Dispensary Registration Certificates.</u>

If the Department does not adopt a formal system to evaluate and rank dispensary applicants, it still must address the limitation on the number of dispensaries. If there are multiple applicants for a dispensary in the same general location and the applications are complete and comply with A.R.S. Title 36, Chapter 28.1 and these rules, the Department should issue the dispensary registration certification to the most qualified applicant.

LIMITATION ON NUMBER OF DISPENSARIES AND SELECTION CRITERIA

A. Limitation on number of dispensaries. The Department may not issue more than one dispensary registration certificate for every ten pharmacies that have registered under A.R.S. § 32-1929, have obtained a pharmacy permit from the Arizona Board of Pharmacy and operate within the State except that the Department may issue dispensary registration certificates in excess of this limit if necessary to ensure that the Department issues at least one dispensary registration certificate in each county in which an application has been approved.

B. Selection process. If the applications for a dispensary registration certificate exceed the number of dispensary registration certificates that the Department may issue, the Department shall issue a dispensary registration certificate to the most qualified applicants. The Department shall consider factors that include, but are not limited to:

1. The strength of the business plan, including whether the business plan demonstrates the ongoing viability of the dispensary as a non-profit organization and demonstrates appropriate oversight and non-profit structure;

2. The strength of security plans and policies for growth, transportation, storage, and dispensing of medical marijuana, including physical security features and security policies and the likelihood that the security will deter fraud, theft, or loss;

3. The strength of the inventory control plans and policies, including whether the applicant is using best available technology to prevent fraud, theft or loss;

4. The strength of the patient records security policies and the patient educational policies; and

5. The strength of dispensing policies and their likelihood to prevent fraud, theft, or loss.

II. THE DEPARTMENT SHOULD REQUIRE DISPENSARIES TO BE CORPORATIONS OR DEFINE PRINCIPAL OFFICER OR BOARD MEMBER.

The residency requirements and other requirements of the rules apply only to "principal officers or board members." The proposed rules do not define these terms. Officers and board members are most often associated with corporations.

The proposed rules seem to contemplate that dispensaries, however, may have a variety of legal forms and leadership governance structures. R9-17-301. Non-profit organizations are usually corporations, which would be required to have a board and officers. The Department should require a medical marijuana dispensary to be formed as a corporation, which would then allow principal officer and board member to have their normal meanings in the corporate context. The regulations in Maine require that dispensaries incorporate under the laws of the State of Maine. The proposed New Jersey regulations also seem to require incorporation, as the application requires submission of the Articles of Incorporation for the dispensary.

The Arizona Medical Marijuana Act defines a medical marijuana dispensary as a "not-for-profit entity" but does not define entity. The Department could define entity in the rule to be corporations duly organized under the laws of the State of Arizona.

If the Department does not require the dispensary to be a corporation, it should define the scope of the people covered by the residency requirement. One definition could be:

> *"Principal officer or board member" means the principal officers or board members of a corporation, the managing member of a member-managed limited liability company or the manager of a manager-managed limited liability company, members of the governing board of an association or cooperative, and other individuals holding the equivalent roles in other types of business organizations.*

III. THE RULES SHOULD CLARIFY WHETHER MEDICAL MARIJUANA IS SUBJECT TO SALES TAX.

The Act and the rules are silent regarding whether there will be a sales tax. There are different practices in the different states that have medical marijuana laws Some of them did not tax medical marijuana initially and are now issuing opinions that the sales are subject to sales tax (see *http://www.coloradoattorneygeneral.gov/sites/default/files/ag_opinions/2009/.pdf_3* for the Colorado attorney general opinion). The Rules should address whether medical marijuana, like prescribed medications, is exempt from sales tax or whether, like tangible personal property, is subject to State and local sales tax.

IV. THE RULES SHOULD REQUIRE BIOMETRIC IDENTIFICATION PRIOR TO DISPENSING MEDICAL MARIJUANA.

In order to prevent fraud and abuse, the Department should require the use of biometric identification, such as fingerprint identification, prior to dispensing medical marijuana

As we are all aware, identification cards are too frequently forged or altered. The only way to insure against fraud and identity theft is to require biometric fingerprint identification prior to dispensing medical marijuana. Photographs and picture IDs can be altered Relatives can often look similar enough to use each other's identification cards (which has enabled minors to purchase alcohol using an older sibling's or cousin's identification). However, an individual cannot fake fingerprints. The only way to ensure that medical marijuana is dispensed only to persons authorized to receive medical marijuana is using fingerprint biometrics. The technology is readily available for all dispensaries to be able to satisfy this requirement.

Based upon a request from law enforcement, the City of Peoria recently discussed requiring biometrics for dispensing of any Schedule I or Schedule II controlled substance by pharmacies in Peoria. Using biometric identification is the way that Peoria police believe that they can control prescription fraud. The same logic applies in the medical marijuana context. Law enforcement favors biometrics to help prevent and detect fraud and abuse

The Department should add a new requirement in R9-17-302(B):

A sworn statement signed and dated by the individual or individuals in R9-17-301 certifying that the dispensary has purchased or will purchase and maintain equipment and software for required to use fingerprint biometrics to verify the identity of all qualifying patients and designated caregivers prior to dispensing medical marijuana.

The Department should modify R9-17-311 dealing with dispensing medical marijuana:

Before a dispensary agent dispenses medical marijuana to a qualifying patient or a designated caregiver, the dispensary agent shall:

1 Verify the qualifying patient's or the designated caregiver's identity using a biometric fingerprint reader;

Biometrics will assist in the prevention of fraud and identity theft by the electronic verification of each cardholder's identity as well as assisting the Department and law enforcement in monitoring and tracking medical marijuana dispensing and patient use of medical marijuana.

V. REGISTRY IDENTIFICATION CARDS SHOULD INCLUDE SECURITY FEATURES TO PREVENT FORGERIES.

Registry identification cards should include security features to prevent forgeries Security features could include optically variable ink graphic film laminate, holographic seals or other visible security features to help identify genuine cards and prevent reproduction. The cards could also use RFID chips or magnetic strips that do not store personal information but that can be linked to the Department database and integrated with a dispensary's electronic

inventory and dispensing records to help the Department and dispensaries track and control the medical marijuana process from seed to sale.

VI. DISPENSARIES SHOULD BE ABLE TO ACQUIRE MEDICAL MARIJUANA IN ANY AMOUNT FROM OTHER DISPENSARIES OR QUALIFYING PATIENTS OR DESIGNATED CAREGIVERS.

A. Requiring Each Dispensary to Cultivate its Own Medical Marijuana Unnecessarily Increases the Number of Cultivation Sites in the State.

By requiring that each dispensary cultivate a minimum of 70% of the medical marijuana it dispenses, the Department would ensure that there will be approximately 125 cultivation sites. It is in the best interest of the State of Arizona and law enforcement to have fewer cultivation sites. The fewer cultivation sites that exist, the easier they will be to monitor and regulate and the prospects for production and inventory control will be enhanced. Rather than requiring each dispensary to cultivate its own medical marijuana, the Department should allow dispensaries to acquire medical marijuana from any other dispensary or qualifying patient or designated caregiver.

There are some capable, professional business people who would be very good at running a secure, effective, fraud-proof dispensary, but who may not necessarily be as good at cultivating medical marijuana. Rather than turning every local dispensary into a grower, the Department should implement rules that would allow the number of cultivation sites to be reduced and for market forces to optimize cultivation.

B. The 70%/30% Rule is Not Effective for Inventory Control.

We understand that the intent of the 70% requirement is to help with inventory control. In reality, this system increases the likelihood of fraud and of medical marijuana being sold on the illegal drug market. This could happen in at least two ways. First, some dispensaries will have too much supply, increasing the chances for fraud or loss and that the lawful medical marijuana could be sold on the illegal drug market. Second, some dispensaries would not always have sufficient stock so excess stock from one dispensary could end up being sold to other dispensaries that are unable to grow sufficient stock or the dispensary would acquire it from the illegal drug market, requiring the dispensaries to fraudulently document transactions to maintain the impression of compliance with the Rules. Dispensaries may end up with too little or too much medical marijuana, which is not effective inventory control.

Having the 70%/30% requirement also interferes with the purpose of the Arizona Medical Marijuana Act, which is to provide relief to persons suffering from debilitating illnesses. If dispensaries are unable to keep fresh, effective stock to dispense to patients because of the 70%/30% rule, they will be unable to further the purposes of the Arizona Medical Marijuana Act. Further, if dispensaries are required to destroy medical marijuana that it cannot sell to other dispensaries, the costs of doing business will increase, which will increase the costs to the patients. If dispensaries are unable to grow sufficient stocks of medical marijuana and cannot acquire medical marijuana from other dispensaries, the patients the Act was designed to help may not be helped. This could be an especially acute problem in rural areas with fewer dispensaries.

A ***free-market system*** in which a dispensary can purchase or sell to any other dispensary as part of a competitive free market is the best way to guarantee the appropriate supply of medical marijuana, to discourage dispensaries from going outside authorized sources to obtain marijuana, and to reduce the incentive or risk of the sale of excess marijuana on the illegal drug market. Effective tracking and controlling of sales between dispensaries is much better inventory control and fraud prevention than is accomplished by requiring each dispensary to have its own cultivation site.

Because the 70%/30% will not be effective, we recommend removing Rule R9-17-307(C)(1) and (C)(5) and revising R9-17-307(C)(4) to read:

4. *May acquire ~~up to 30% of~~ the medical marijuana the dispensary provides to qualifying patients and designated caregivers from another dispensary in Arizona, a qualifying patient, or a designated caregiver.*

C. **Electronic Tracking from Seed to Sale is Better Inventory Control and Fraud Prevention than Requiring Each Dispensary to Cultivate its Own Medical Marijuana, and the Department Should Require Dispensaries to Provide the Department with Access to the Tracking and Inventory System.**

In order to keep track of sales and medical marijuana inventory, to prevent fraud, and to minimize the possibility of loss or theft, the Department should require real-time electronic tracking of the medical marijuana from seed to sale.

The proposed draft rules would require that dispensaries establish an inventory control policy, A.A.C. R9-17-307(1)(c), and require that their inventory control system identify certain minimum information. A.A.C. R9-17-313. The proposed rules do not identify how dispensaries are required to maintain the records, leaving it entirely up to the dispensary how to track the information and record it. This opens the door for significant fraud, as paper records can be more easily manipulated than a verifiable electronic tracking and inventory system.

Real-time electronic tracking of medical marijuana from seed to sale—using an electronic system that can be accessed and reviewed by the Department—will be more effective than allowing each dispensary to establish its own inventory control and tracking methods. Appropriate language revisions are:

Modify R9-17-313(B) as follows:

A dispensary shall establish and implement an *electronic* inventory control system *to track, monitor and report the following* for the dispensary's medical marijuana ~~that documents~~:

Modify R9-17-313(D) as follows:

2. *Provide the documentation required in subsections (B) and (C) to the Department for review upon request, and provide the Department with access, including remote access, to the dispensary's electronic inventory control system upon request.*

D. **The Department's Inspection Authority Should Require Electronic Inventory and Include Unannounced Access to Electronic Tracking and Inventory Control Systems.**

In addition to requiring electronic tracking and inventory control, the Department should add to the inspection requirement that its authority to conduct unannounced inspections includes the authority to access the electronic tracking and inventory control system.

An integrated electronic and technologically advanced system that allows real-time tracking of patient usage, each dispensary's dispensing of medical marijuana, verification that physician statements and cards are un-expired prior to dispensing to patients, and inventory control and management is critical to a stable, secure, and fraud-proof medical marijuana system. The technology is currently available in the medicine dispensing software market to allow dispensaries to electronically record and track all inventory and transactions.

This system would allow the Department better auditing capabilities. It will allow the Department to conduct audits remotely to do an electronic audit. This would also prevent potential HIPAA violations and invasion of client privacy involved in potentially monitoring cameras and reviewing individual patient files.

VII. THE RULES SHOULD EXPRESSLY PERMIT DISPENSARIES TO DEVELOP ELECTRONIC SYSTEMS TO INTERACT WITH AND PROVIDE INFORMATION TO THE STATE'S MEDICAL MARIJUANA ELECTRONIC VERIFICATION SYSTEM

The proposed rules require a dispensary agent to verify information from the State's medical marijuana electronic verification system and enter additional information into the system relating to the transaction. The technology is available to allow this process to be automated so that the dispensary computer directly communicates with the medical marijuana electronic verification system without a human user being required to enter the information. This automatic communication from computer-to-computer would reduce the chances of human error while reviewing or inputting information, and thus better prevent fraud and improper dispensing of medical marijuana. It would also mean that human users could not alter or enter fraudulent information, again reducing the chances for fraud or abuse of the medical marijuana system.

The rules should explicitly allow such electronic transactions by making the existing R9-17-311 part A and adding as part B:

> *B. A dispensary may use an automated electronic system of hardware and software to verify the information required in Section A before dispensing medical marijuana to a qualifying patient or designated caregiver and to submit the required information to the medical marijuana electronic verification system.*

VIII. THE REQUIREMENT THAT A DISPENSARY BE READY FOR INSPECTION BY DHS PRIOR TO AN APPLICATION BEING CONSIDERED COMPLETE IS AN UNNECESSARY BURDEN TO APPLICANTS WHOSE APPLICATION MAY NOT BE APPROVED AND UNNECESSARILY DELAYS THE OPENING OF DISPENSARIES.

A. The Department Should Issue Preliminary Approval for Dispensary Registration Certification Prior to Inspection.

It is unclear in the Rules whether the Department may issue a preliminary approval of dispensary registration certificate prior to a dispensary being ready for inspection by the Department. The rules require that the applicant identify whether the site is ready for inspection or identify the date on which it will be ready A.A.C. R9-17-302. Another rule, however, states that an application for a dispensary registration certificate is not complete until the applicant provides written notice to the Department that the dispensary is ready for inspection A.A.C. R9-17-302 This would make it appear that *before* the Department will review an application and provide preliminary approval of a dispensary registration certificate, the applicant must go through the time and expense to complete the construction and build out of the dispensary and cultivation site with the required security and physical plant requirements. In addition to the time and money spent building out the property, this would also require obtaining permits from the municipal or county government where the dispensary will be located, which could again delay the process.

Requiring a complete build-out before the Department deems the application complete will place all dispensary applicants in the situation where they must spend a great deal of time and money with no guarantee that they will receive a dispensary registration certificate. This is wasteful, unnecessary, and places an undue burden on dispensary applicants.

The Department should review applications and issue preliminary approval based on floor plans, security plans, etc. After a dispensary applicant receives preliminary approval, final approval could be contingent upon an inspection demonstrating that the dispensary has fully implemented floor plans, security, zoning, and other elements of the building proposal. The Department could allow for 120 days after notice of preliminary approval for the dispensary to be completed and ready for inspection

The Department should eliminate the proposed rule R9-17-107(B). The Department should revise Section R9-17-107(F)(1) so that it reads as follows:

1 *Within 120 calendar days* after the applicant receives the written notice of preliminary approval, the applicant shall submit to the Department:

(a) Written notice that the dispensary and cultivation site, if applicable, are ready for inspection by DHS;

(b) An application for a dispensary agent registry identification card . .

The Department should also revise Section R9-17-107(F)(2) so that it reads as follows:

2 After receipt of the information and documents in subsection (F)(1) *and after completing an inspection of the dispensary and cultivation site, if applicable,* the Department shall review the information and documents, and if the *inspection of the dispensary and cultivation site, if applicable, demonstrated compliance with A.R.S. Title 36, Chapter 28.1 and these Rules and the* information and documents for at least one of the principal officers or board members complies with the A.R.S. Title 36, Chapter 28.1 . . .

Because it may not be possible to determine a date on which a site will be ready for inspection at the time of the application, R9-17-302(B)(1)(j)-(k) should be eliminated. The only dispensary applicants required to provide notice that the dispensary is ready for inspection would be those who have received preliminary approval.

In this way, applicants will still be required to have identified and secured a location that complies with the zoning laws and restrictions on placement of dispensaries and have established a plan for compliance with the Arizona Medical Marijuana Act and implementing rules, but the dispensary is not necessarily required to go through the expense of building out the space and acquiring all of the security features prior to knowing that the dispensary may be able to acquire a dispensary registration certificate

B. **The Applicant Should be Permitted to Identify a Cultivation Site or Source After the Preliminary Approval.**

As discussed above, it is better to allow each dispensary to obtain medical marijuana in any amounts from other medical marijuana dispensaries. Dispensaries should be required to have a plan for acquiring sufficient supplies of medical marijuana to serve their patients. Requiring a physical address for a cultivation site prior to application, however, could delay the application process and the build-out of medical marijuana dispensaries. The rules should provide for dispensaries with otherwise complete applications, time after preliminary approval to identify a separate cultivation facility that is properly zoned and for which the applicant obtains a certificate of occupancy or other required documentation.

The Rule could permit an applicant who has not identified an off-site cultivation source to provide the Department with notice of a cultivation site that is separate from the dispensary after preliminary approval. Preliminary approval could be contingent upon the cultivation site also being ready for inspection within 120 days after the Department provides preliminary approval to the dispensary. Approval could also be contingent on the submission of information about the cultivation site within 60 days after notice of preliminary approval.

Language to use for a revised R9-17-301(B)(1)(h) is below:

Whether the dispensary will cultivate medical marijuana at the dispensary site or at a cultivation site, and if at a cultivation site the physical address of the dispensary's cultivation site or a statement that the dispensary intends to obtain a cultivation site in compliance with all local zoning ordinances;

C. **Revising the Rule to Expedite Dispensary Approvals Will Reduce the Number of Patients and Caregivers Growing Their Own Marijuana, which is Beneficial to the Department, Law Enforcement, and the State.**

Revising the proposed Rule will also help dispensaries be operating quicker, as the application will be considered complete and be considered by DHS sooner. This will benefit the State, law enforcement, and the

Department, because the sooner the dispensaries are operative, the sooner qualifying patients will be prohibited from growing their own medical marijuana if they live within 25 miles of a dispensary. Dispensaries can submit completed applications—to be processed within the timelines set out in the rules—prior to completing build-out of their facilities, which will expedite the processing of applications, which in turn means fewer individuals cultivating their own medical marijuana. If every applicant has to have a completed structure—with all security and physical requirements met—before the Department considers the application complete, it could be several months before any dispensary applications are complete, causing significant delays in dispensaries being opened.

During the period of time that the Department is reviewing dispensary applications, all qualifying patients or designated caregivers will be able to grow their own medical marijuana, because when no dispensaries exist every patient will be more than 25 miles from a dispensary. This is not a desirable situation, as the Department has less control and oversight over home growers than it does dispensaries. There is much greater potential for fraud and abuse if there are more people growing their own medical marijuana than if they are obtaining it from a regulated dispensary. Therefore, it is in the best interest of the Department to make rules that will expedite the ability of dispensaries to become operative across the State more quickly.

IX. THE RULES SHOULD CONTAIN GREATER SECURITY REQUIREMENTS RELATING TO STORAGE OF MEDICAL MARIJUANA AT DISPENSARIES.

In order to deter theft and abuse, the Rules should require that medical marijuana supplies that are stocked in a dispensary during the day are stored in a safe or other locked, limited access area during non-work hours and are not left on shelves overnight.

The Department could add a new requirement to R9-17-315:

D. Storage of Marijuana. During non-business hours, medical marijuana that is prepared for distribution shall be stored securely in compliance with 21 C.F.R. 1301.72, as amended and supplemented.

The Code of Federal Regulations provides more specific detail on the types of safe or storage facilities that are required for Schedule I and II controlled substances, and requiring this type of storage is consistent with the requirements placed on other lawful medications that are Schedule I or Schedule II controlled substances.

Alternatively, as part of Section R9-17-315, the following language could be added:

(C)(2)(f) For storing medical marijuana that is prepared for distribution in a safe, vault, or other similar locked, secure, and limited access storage container during non-working hours.

(C)(3) A safe, vault, or other similar locked, secure, and limited access storage container for storage of medical marijuana that is prepared for distribution and stored at the dispensary during non-working hours.

If medical marijuana is left stocked on dispensary shelves or otherwise readily accessible by breaking into a dispensary business, it could encourage more break-ins and theft than if dispensaries were required to remove and lock away the medical marijuana during non-business hours.

X. THE RULES SHOULD CONTAIN SECURITY REQUIREMENTS FOR THE TRANSPORTATION OF MEDICAL MARIJUANA.

The proposed rules expressly permit the transportation of medical marijuana, plants, and paraphernalia, but places absolutely no security requirements on the transportation. This leaves a big gap when the marijuana could be the most vulnerable. Colorado and New Jersey have proposed regulations relating to the transportation of medical marijuana. Maine also has regulations that address transportation.

At a minimum, the Department should add as part of Section R9-17-315(C)(2) a requirement that the dispensary create policies relating to transportation:

That provide for safely transporting marijuana in any form, marijuana plants, and marijuana paraphernalia between the dispensary and:

1. *The dispensary's cultivation site,*

2. *A qualifying patient,*

3. *Another dispensary, and*

4. *A food establishment contracted with the dispensary to prepare edible food products infused with medical marijuana.*

Taking a combination of the requirements in other states, the Department could implement an on-line reporting and tracking system for medical marijuana and adopt the following new rules relating to the transportation of marijuana, which could be added at R9-17-315(B)(2)and renumber the existing Section B to be Section (B)(1), as follows:

1. *When a dispensary transports marijuana in any form, marijuana plants and marijuana paraphernalia:*

    a. *Vehicles used for transporting marijuana in any form, marijuana plants, and marijuana paraphernalia shall bear no identifying marking;*

    b *The dispensary agent staffing the vehicle must have access to a form of secure telecommunications with the dispensary, such as a cellular phone;*

    c. *Marijuana in any form, marijuana plants, and marijuana paraphernalia must be secured and protected during transportation and may not be visible from outside of the vehicle;*

    d. *The dispensary agent staffing each vehicle must have a trip inventory, created and submitted online using a form approved by the Department and printed for retention with the marijuana products being transported, that includes the following information:*

        i. *the name and address of the dispensary;*

        ii. *the origin and destination of the medical marijuana;*

        iii. *the name and registry identification number of the dispensary agent staffing the vehicle;*

        iv. *the route to be traveled;*

        v. *the time and date of transportation;*

        vi. *the make, model and license plate number of the vehicle being used for transport; and*

        vii. *the amount and form of marijuana and marijuana material that is being transported.*

    e. *When determining and reporting the route to take, dispensaries should select the best direct route that provides efficiency and safety.*

The Department should require an electronic inventory and tracking system that will be used during the entire stage of the process, including before transportation, during transportation, and upon delivery to the intended destination. There is currently available and affordable technology that can perform this function. An electronic tracking and reporting system to be used before and during transportation of the medical marijuana and upon delivery to the destination will assist the Department and law enforcement with enforcing the Arizona Medical Marijuana Act

and will help ensure that medical marijuana is properly dispensed and does not become a part of the illegal drug market.

XI. THE RULES SHOULD CONTAIN CERTIFICATION OR SECURITY REQUIREMENTS FOR FACILITIES INFUSING MEDICAL MARIJUANA INTO FOOD PRODUCTS.

A. Additional Requirements Need to be Placed on Entities Infusing Medical Marijuana Into Food Products.

The rules need to address more specifically the preparation of medical marijuana-infused food products. It is not clear from the proposed rules what, if any, limits or requirements are placed on the facilities or persons preparing the medical marijuana food products aside from holding a valid food establishment permit and working under contract with the dispensary.

The Act and the proposed rules require that each individual employed by or contracted with a dispensary must have a dispensary agent registry identification card before working at the dispensary. A A C. R9-17-308; A R S § 36-2804.01 Does this requirement extend to the companies who infuse medical marijuana into food products, as the rules require that they be under contract to the dispensary? What is the definition of "under contract?" What if the contract is with an entity, not an individual? Is the entity an "agent" of the dispensary that is able to receive a dispensary agent registry identification card?

Although R9-17-316 contains very little information relating the limitations and requirements on food facilities infusing medical marijuana into edible food products, other sections of the proposed rules seem to suggest that the persons handling medical marijuana at a food establishment would be the agents of a dispensary. For example, R9-17-307(A)(4)(d) requires that the dispensary not allow an individual who does not possess a dispensary agent registry identification card issued under the dispensary's registration certificate to have access to medical marijuana at a food establishment contracted to infuse medical marijuana into food products. This raises several issues. One problem is that many food establishments are entities, not individuals, but it appears from the rules that only individuals can be dispensary agents. Another problem is that the food establishment would be the employer of the individuals working at that establishment, not employed by or supervised the dispensary, making it difficult for the dispensary to control those individuals.

The lack of regulation of facilities infusing medical marijuana products raises several additional issues. What kind of inventory control is really taking place? What ensures that the medical marijuana is infused in the amounts that are represented to the dispensary? What ensure the quality of the performance? Is it the intent of the Department that these issues will be solely regulated by the contract between the dispensary and the food establishment?

At a minimum, the regulations should identify some of the required elements of a contract between a dispensary and a food establishment. The proposed regulations in Colorado require the Medical Marijuana Enforcement Division to approve the form and substance of such contracts. The Department should consider doing the same by adding a rule R9-17-316(C):

> *C. Any contract required pursuant to R9-17-316(A)(1) must be approved as to form and substance by the Department.*

B. The Rules Should Allow a Dispensary to Obtain Medical Marijuana Infused Food Products From Other Dispensaries.

The current proposed rules seem to contemplate that a dispensary will provide medical marijuana to a licensed food preparing facility and will sell only those infused food products that are produced using marijuana provided by the dispensary. There is no logical reason to prevent a medical marijuana dispensary from acquiring medical marijuana-infused food products from another dispensary, as the rules already allow dispensaries to obtain medical marijuana from another dispensary. The medical marijuana-infused food products should be permitted to be sold between

dispensaries (as long as properly labeled, etc.), as part of the market system for sales between dispensaries that we discussed in our comments above.

The Department should revise R9-17-307(C)(2) as follows:

Shall only provide medical marijuana cultivated or acquired by the dispensary *or edible food products infused with medical marijuana made or acquired by the dispensary* to another dispensary in Arizona, a qualifying patient, or a designated caregiver authorized by A.R.S. Title 36, Chapter 28.1, and this Chapter to acquire medical marijuana

XII. THE RULES SHOULD EITHER REMOVE OR DEFINE "INDIVIDUAL . . . CONTRACTED WITH" IN RELATION TO A DISPENSARY AGENT SO IT IS CLEAR THAT CORPORATIONS AND OTHER LEGAL ENTITIES PROVIDING SERVICES TO THE DISPENSARY ARE NOT "AGENTS" WHO REQUIRE A DISPENSARY AGENT CARD.

In R9-17-101(9), the proposed rules define "dispensary agent" to mean the same as "nonprofit medical marijuana dispensary agent" as defined in A.R.S. § 36-2801. The Act defines "nonprofit medical marijuana dispensary agent" as a principal officer, board member, employee or volunteer of a nonprofit medical marijuana dispensary who is at least twenty-one years of age and has not been convicted of an excluded felony offense. However, in Section R9-17-308 a dispensary is required to apply for a dispensary agent registry identification card for individuals "contracted with" the dispensary. The definitions of dispensary agent in the Act and in the rules do not include an individual "contracted with" a dispensary. Therefore, the Department should remove "contracted with" from R9-17-308, as it is outside of the scope of the definition of dispensary agent.

If "contracted with" is not removed from the rule, then it should be clarified. The proposed rules require a dispensary agent identification card for an "individual . . . contracted with" a dispensary. The rules do not define the term "individual." Individual is generally understood to be a human person, and it is used throughout the rules in contexts in which it clearly means a physical person, not a legal entity. Nevertheless, the rules should clarify that an agent is an individual person, not another legal entity. For example, if a company provides accounting services, advertising services, cleaning services, consulting services, etc. to a dispensary, the company providing the services is generally "under contract" with the dispensary. There is a contractual relationship. The service provider, however, is not an agent of the dispensary that can act on the dispensaries behalf and should not be considered a dispensary agent for purposes of the Arizona Medical Marijuana Act.

The rules for dispensary agent identification card applications clearly contemplate that the agent will be a single, live person and not any other form of entity, but the Department should clarify this requirement.

XIII. THE RULES SHOULD ALLOW ONE SIGNATURE ON DISPENSARY APPLICATIONS.

The Department should eliminate the proposed rule (R9-17-301) relating to individuals to act for the dispensary for two primary reasons. First, as discussed above, the dispensaries should be required to be corporations, and therefore there is no need to identify who in other business formations would act for the dispensary. Second, it is a general principle of corporate law that one corporate officer can bind the corporation. It could delay processing of applications and the responsiveness of the applicants if they are required to obtain multiple signatures for all documents and information submitted to the Department. Additionally, it is lawful to establish a corporation with the same individual acting in all officer roles. One authorized signature is legally binding on an entity and the Department should not require more. Therefore, the Department should delete R9-17-301 or revise so that in each section requiring two signatures it will require only one signature.

XIV. THE ARIZONA MEDICAL MARIJUANA ACT PROVIDES SHORTER TIMELINES FOR ISSUING A DISPENSARY REGISTRATION CERTIFICATE THAN ARE PROVIDED IN THE RULES.

The Arizona Medical Marijuana Act requires that DHS issue a dispensary registration certificate "not later than ninety days after receiving an application" that is complete and satisfies the Act and rules. A.R.S. § 36-2804. In R9-17-107, the proposed rules provide the Department with 90 working days, rather than 90 calendar days, as the timeframe in which to issue a dispensary registration certificate. Because the Act does not specify calendar days or working days, the Act should be given the common usage of "days"—which is calendar days, not working days.

A.R.S. §1-213 establishes that in interpreting statues, if there is no specific definition, "words and phrases shall be construed according to the common and approved use of the language." The common usage of 90 days is 90 calendar days. The difference in processing time could be almost 6 weeks if the Rules use 90 working days (18 weeks if there are no holiday or furlough days) as opposed to 90 calendar days (just over 12 weeks).

Additionally, the proposed rules identify the overall time frame for processing the dispensary registration certificate as 90 working days. The rules require a preliminary approval notice to be issued if the application is complete, then the applicant submits dispensary agent registry card applications for the principal officers and board members before the dispensary registration certificate is issued. There could be some confusion regarding whether the preliminary approval notice must be issued within working 90 days or the actual registration certificate must be issued within 90 working days, although the table indicates that 90 working days is for completing the entire process.

Consequently, the language in R9-17-107 should be revised to state calendar days rather than working days for processing dispensary applications.

XV. THE REQUIREMENTS AND LIMITATIONS ON THE MEDICAL DIRECTOR EXCEED THE DEPARTMENT'S RULEMAKING AUTHORITY AND MAY NEGATIVELY IMPACT THE ABILITY OF DISPENSARIES TO OBTAIN A MEDICAL DIRECTOR.

A. The Limitation on the Medical Director Being an MD or DO Exceeds the Department's Rulemaking Authority.

The limitation on a medical director being an MD or DO exceeds the Department's rulemaking authority, as it is inconsistent with the Act's broad definition of physician to include naturopaths and homeopaths. There is no logical reason for allowing naturopaths and homeopaths to provide recommendations for patients but not to act as the medical director of the dispensary where the patient obtains the medical marijuana. Additionally, nurse practitioners in the State of Arizona can act as primary care doctors and write prescriptions. The State of Arizona treats nurse practitioners as physicians for most purposes. Therefore, the rule should also be expanded to include nurse practitioners.

Additionally, because marijuana is still illegal on the federal level, licensed physicians may be reluctant to serve as a medical director of a medical marijuana dispensary. This could limit the number of people available to serve as a medical director. The problem could be worse in rural areas where there are fewer physicians. This supports expanding the medical director definition to include homeopaths, naturopaths, and nurse practitioners.

In order to ensure that each applicant can obtain the services of a qualified person to serve as medical director, the Department should define physician to include a homeopath, naturopath or nurse practitioner.

The Department should therefore revise the definition of medical director in R9-17-101(15):

"Medical director" means a doctor of medicine who holds a valid and existing license to practice medicine pursuant to title 32, chapter 13 or its successor, a doctor of osteopathic medicine who holds a valid and existing license to practice osteopathic medicine pursuant to title 32, chapter 17 or its successor, a naturopathic physician who holds a valid and existing license to practice naturopathic medicine pursuant to title 32, chapter 14 or its successor or a homeopathic physician who holds a valid and existing license to practice homeopathic

medicine pursuant to title 32, chapter 29 or its successor, or a nurse practitioner who holds a valid and existing license to practice as a nurse practitioner pursuant to Title 32, Chapter 15 or its successor and who has been designated by a dispensary to provide medical oversight at the dispensary.

B. **The Limit on a Medical Director Acting for Only Three Dispensaries is Unnecessarily Limiting and Could Adversely Impact the Ability of a Dispensary to Obtain the Services of a Medical Director.**

Because medical directors are required only to be available to be contacted as needed, there is no logical reason to limit a medical director to serving only three dispensaries. Some dispensaries may serve fewer patients and not need as much time and attention from the medical director, while others may be busier. The dispensary and medical director should be able to determine if the medical director is providing the appropriate time and attention to the dispensary. If the Department believes it necessary to impose a limit, the Department should limit the number of dispensaries that a medical director can serve to 10 dispensaries.

Further, as discussed above, there may be reluctance on the part of some physicians to serve as a medical director, making it difficult to procure the services of a medical director if the medical director is limited to working in three dispensaries.

Many of the processes in the dispensary could easily be automated. A medical director could oversee the development of electronic pain records for qualifying patients and caregivers to use and it would not require extensive time for the medical director to oversee this electronic system. The record keeping and oversight could also be mostly electronic. The use of electronic and automated systems would allow a medical director to act effectively and efficiently on behalf of more than three dispensaries. Because of the specialized nature of serving as a medical director and the extents of regulatory requirements, greater compliance may be achieved if medical directors are permitted to serve more than three dispensaries. Otherwise, medical directors serving one, two, or three dispensaries may not devote as much time to such duties and their expertise in the medical and regulatory environment in which the dispensaries operate may be less than someone who develops a greater specialty and expertise in the area. The arbitrary limit to three dispensaries is unnecessary.

Therefore, in order to ensure that each applicant can obtain the services of a qualified person to serve as medical director, the Department should remove the limit on the number of dispensaries that one medical director can serve. The Department should revise R9-17-310(A):

A medical director may only serve as a medical director for ~~three~~ *ten* dispensaries at any time

XVI. THE DEPARTMENT'S DEFINITION OF "ONGOING" FOR A PHYSICIAN-PATIENT RELATIONSHIP ATTEMPTS TO TELL DOCTORS HOW THEY MUST PRACTICE, IS UNNECESSARILY ONEROUS, AND INTERFERES WITH THE PURPOSES OF THE ACT.

Federal law requires a bona fide doctor-patient relationship before a physician prescribes a controlled substance. The same requirement should apply for medical marijuana recommendations, but the definition proposed by the Board, in R9-17-101(16)(a), which requires four visits over the span of a year, may prevent some patients from obtaining the relief offered by the Medical Marijuana Act in a timely manner. Arizona common law already has standards for determining when a doctor-patient relationship exists, for example in the context of medical malpractice torts or duties of confidentiality. It takes significantly less than one year to establish a bona fide doctor-patient relationship under existing legal standards.

Principles of medical ethics also have standards for the doctor-patient relationship and the dispensing of medication. Doctors are bound to follow their medical ethics in making recommendations for medical marijuana. It would violate their ethical standards to make recommendations for medical marijuana without conducting a proper examination of the patient's health and history. Excessive government regulation, such as rules that tell the doctor how

to practice – including how many visits or length of treatment – overstep the bounds of this rulemaking. Doctor's ethical standards, not government rules, should control the doctor-patient relationship.

Part B of the definition of "ongoing," in R9-17-101(16)(b), is good to an extent, but it could prevent U.S. military veterans whose primary care physicians are at the Veterans Administration Hospitals from being able to acquire medical marijuana if it would provide them relief from a debilitating medical condition. Doctors at the Veterans Administration are not permitted to write recommendations for medical marijuana because it is still proscribed by federal law. Yet many veterans cannot afford to move their primary health care for a debilitating condition to an outside doctor. The rules should be revised to allow veterans – or others with limited means – to receive evaluation and recommendations from other physicians without transferring long-term, ongoing care to another physician. Many military veterans are suffering from debilitating conditions because of their military service. The State should take extra steps to ensure that these veterans are able to obtain the care and benefits provided by the Arizona Medical Marijuana Act.

As there are already existing legal and ethical guidelines for when a physician-patient relationship is established and because the definitions proposed by the Department would make it unnecessarily difficult for a person with a genuine medical need to obtain medical marijuana–and make it virtually impossible for veterans using the services of a VA Hospital–the Department should eliminate the definition of "ongoing" in the proposed rules at R9-17-101(16) and require a bona fide doctor-patient relationship. Sample language to achieve this revision to be added in R9-17-101 and replace "physician-patient relationship" (with corresponding changes throughout the rules) is:

"Bona fide physician-patient relationship" means

(i) a physician and a patient have a treatment or counseling relationship, in the course of which the physician has completed a full assessment of the patient's medical history and current medical condition, including an appropriate personal physical examination and a personal review of the patient's medical record maintained by other treating physicians that may include the patient's reaction and response to conventional medical therapies;

(ii) the physician has consulted with the patient with respect to the patient's debilitating medical condition before the patient applies for a registry identification card; and

(iii) the physician is available to or offers to provide follow-up care and treatment to the patient, including but not limited to patient examinations, to determine the efficacy of the use of medical marijuana as a treatment of the patient's debilitating medical condition.

XVII. WHERE RESIDENCY IS NOT A REQUIREMENT, THE PERMISSIBLE IDENTIFICATION PROVIDED TO OBTAIN A REGISTRY IDENTIFICATION CARD SHOULD BE EXPANDED.

The proposed rules require in R9-17-107(F)(1)(d) and R9-17-308(5) that an applicant for a dispensary agent registry identification card provide either an Arizona driver's license or identification card issued after October 1, 1996, an Arizona registry card, a US passport photo page, or an Arizona ID issued prior to October 1, 1996 with additional proof of U.S. citizenship. We realize that the State is required to verify lawful presence in the U.S. prior to awarding any license or benefit. However, because there is no requirement that the dispensary agents (other than principal officers and board members) be Arizona citizens, the list of acceptable documents should be expanded to add as permissible identification the following:

- *valid driver's license or identification card from another state whose qualification requirements are as strict as those of the state of Arizona*

- *valid driver's license or identification card from another state whose qualification requirements are not as strict as those of the state of Arizona and one of the following:*
    - *(list same documents as required to accompany Arizona license prior to 1996)*

XVIII. MISCELLANEOUS COMMENTS.

There is an inconsistency between R9-17-107(C)(2) and (C)(3). Section (C)(2) provides an applicant 60 *working* days to provide missing information or documents after a notice of deficiency Section (C)(3) provides that if the information is provided within 60 *calendar days*, then substantive review starts after the documents are received. It appears that the two sections should use the same time frame, and calendar days would be the appropriate measure, as discussed previously in these comments

Section R9-17-108(3)(a) contains a reference to written notification required from a dispensary when a dispensary agent is no longer associated with the dispensary and says that R9-17-306(A)(5) sets out this requirement. Section R9-17-306(A) is inspections. The Rule should be R9-17-**307(A)(5).**

XIX. CONCLUSION.

Arizona should set the strictest requirements for safety, security and fraud prevention that any state has yet established. Arizona has the opportunity to do what no state has yet done: establish a safe, secure, efficient, and virtually fraud-proof system for the cultivation, sale, and use of medical marijuana. The State has a chance to avoid the pitfalls that other states have encountered in enforcing their medical marijuana laws Arizona should get the rules right the first time so that it has an effective medical marijuana program that balances all the competing interests and assists law enforcement to continue to enforce criminal drug laws while allowing medical marijuana patients the relief that the Act intended to provide. Having the best possible rules at the outset is crucial, as it will be more difficult to change practices later than to establish the best practices at the beginning of the program.

The Department is to be commended for the excellent job it has done in a very short period of time, with limited resources, to prepare a comprehensive set of proposed rules The Department's circulation of draft proposals is extremely beneficial, as it has permitted early input and suggestions from parties interested in this process. We hope these recommendations are helpful and will be incorporated into the remainder of the rulemaking process in order to best serve the interests of all affected parties in Arizona.

Sincerely,

Dr Bruce Bedrick
CEO

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Sincerely,

Bruce Bedrick DC

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Arizonans Concerned About Smoking

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Our Purpose Is To Save Lives

January 6, 2011

[redacted]

Mr. Will Humble, Director
Arizona Department of Health Services
150 N. 18th Avenue
Phoenix, AZ 85007

Dear Mr. Humble:

As stated earlier, Arizonans Concerned About Smoking (ACAS) is very appreciative of your respected leadership in developing the health based guidelines for implementation of AZ Proposition 203.

Our organizational recommendations can be summarized as follows:

1. Honesty in labeling requires that written potential toxicity warning labels be attached to all products dispensed at marijuana dispensaries including cancer warnings when crude marijuana is smoked.

2. The written warnings must include documentation, both as sound medical advice and for medico-legal protection for the State of Arizona in case of adverse toxicity drug reactions or highway accident lawsuits from patients. Information inserts should clearly inform that FDA Federal Drug Policy does not support the smoking form of marijuana for any medical purpose (see attached US-FDA Statement) which is recommended as an insert with each marijuana product dispensed.

3. In addition to a Medical Director for each dispensary, a Pharmacist Expert on drug toxicity and interactions should be assigned to each dispensary.

4. For public safety reasons, organizations responsible for public transportation and community safety currently or in the future maintaining a 100% drug free policy requirement (24/7) daily for employees should be allowed to continue this safety based policy.

5. Current Arizona Voter Initiative Smoke Free Policies relative to hospitals, other health care facilities, other public service facilities, workplaces, and public gathering places will continue to be smoke free from marijuana smoke pollution the same as applies to tobacco smoke.

Respectfully,

Leland L. Fairbanks

Leland L. Fairbanks, MD, MPH
President, Arizonans Concerned About Smoking
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Tel 480: 820-3740, e-mail; acasinc@msn.com

Enclosure

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

News & Events

NEWS RELEASE

FOR IMMEDIATE RELEASE
April 20, 2006

Media Inquiries:
FDA Press Office, 301-827-6242
Consumer Inquiries:
888-INFO-FDA

Inter-Agency Advisory Regarding Claims That Smoked Marijuana Is a Medicine

Claims have been advanced asserting smoked marijuana has a value in treating various medical conditions. Some have argued that herbal marijuana is a safe and effective medication and that it should be made available to people who suffer from a number of ailments upon a doctor's recommendation, even though it is not an approved drug.

Marijuana is listed in schedule I of the Controlled Substances Act (CSA), the most restrictive schedule. The Drug Enforcement Administration (DEA), which administers the CSA, continues to support that placement and FDA concurred because marijuana met the three criteria for placement in Schedule I under 21 U.S.C. 812(b)(1) (e.g., marijuana has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and has a lack of accepted safety for use under medical supervision). Furthermore, there is currently sound evidence that smoked marijuana is harmful. A past evaluation by several Department of Health and Human Services (HHS) agencies, including the Food and Drug Administration (FDA), Substance Abuse and Mental Health Services Administration (SAMHSA) and National Institute for Drug Abuse (NIDA), concluded that no sound scientific studies supported medical use of marijuana for treatment in the United States, and no animal or human data supported the safety or efficacy of marijuana for general medical use. There are alternative FDA-approved medications in existence for treatment of many of the proposed uses of smoked marijuana.

FDA is the sole Federal agency that approves drug products as safe and effective for intended indications. The Federal Food, Drug, and Cosmetic (FD&C) Act requires that new drugs be shown to be safe and effective for their intended use before being marketed in this country. FDA's drug approval process requires well-controlled clinical trials that provide the necessary scientific data upon which FDA makes its approval and labeling decisions. If a drug product is to be marketed, disciplined, systematic, scientifically conducted trials are the best means to obtain data to ensure that drug is safe and effective when used as indicated. Efforts that seek to bypass the FDA drug approval process would not serve the interests of public health because they might expose patients to unsafe and ineffective drug products. FDA has not approved smoked marijuana for any condition or disease indication.

A growing number of states have passed voter referenda (or legislative actions) making smoked marijuana available for a variety of medical conditions upon a doctor's recommendation. These measures are inconsistent with efforts to ensure that medications undergo the rigorous scientific scrutiny of the FDA approval process and are proven safe and effective under the standards of the FD&C Act. Accordingly, FDA, as the federal agency responsible for reviewing the safety and efficacy of drugs, DEA as the federal agency charged with enforcing the CSA, and the Office of National Drug Control Policy, as the federal coordinator of drug control policy, do not support the use of smoked marijuana for medical purposes.

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January 5, 2011

RECEIVED
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ADHS
DIRECTORS OFFICE

Will Humble, Director
Arizona Department of Health Services
150 North 18th Avenue, Suite 500
Phoenix, Arizona 85007-3247

Re: Comment on Draft Rules regarding Medical Marijuana

Dear Mr Humble,

Our law firm intends to be on the forefront of the Medical Marijuana issue as pertains to the enforcement of laws and rules. As such, we have looked closely at the laws enacted under voter initiative in Proposition 203 and the December 17, 2010 draft rules published by the Department of Health Services.

As part of our analysis, we have looked at the application of Proposition 105 passed in November, 1998, that amended the Arizona Constitution. Specifically, we looked at Article IV, Part 1, § 1(6)(C) of the Arizona Constitution that reads:

> **Legislature's power to amend initiative or referendum.** The Legislature shall not have the power to amend an initiative measure approved by a majority of the votes cast thereon, or to amend a referendum measure decided by a majority of the votes cast thereon, unless the amending legislation furthers the purposes of such measure and at least three-fourths of the members of each house of the Legislature, by a roll call of ayes and nays, vote to amend such measure.

In addition, we note that the authority of the Department of Health Services to make rules, such as those authorized by Proposition 203, arises from A.R.S. § 36-136(F). That statute was enacted by the legislature and any rules made pursuant to that statute would be subject to the restrictions imposed on the legislature by the Arizona Constitution. As the legislature needed only a simple majority to pass that statute, any rule created that is does not further the purpose of Proposition 203 would be unconstitutional.

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We believe Proposition 203, as passed by the voters, was intended to allow the use of medical marijuana with only restrictions enumerated in the statutes that were enacted by Proposition 203. Any restrictions making the cultivation, distribution, or use of medical marijuana more onerous than those included in Proposition 203 would violate the Arizona Constitution.

We are of the opinion that any rules made by the Department of Health Services must comply with the quoted section of the Arizona Constitution in that they must further the purpose of Proposition 203. I that light, we comment on the Draft Rule as follows:

1) Draft Rule R9-17-101(15) defines "Medical Director." Draft Rule R9-17-302(B)(1)(g) requires a dispensary to include the name and license number of its medical director on an application for a Dispensary Certificate. Draft Rule R9-17-307(A)(3) requires a dispensary to employ or contract with a medical director. Draft Rule R9-17-310 specifies duties and restrictions of medical directors.

   Neither the term "Medical Director" nor any description of qualifications, duties, and restrictions of medical directors appears in the laws included in Proposition 203. We believe that requiring a dispensary to employ or contract with a medical director conflicts with the Arizona Constitution because it places requirements on dispensaries more onerous than those included and does not further the purposes of Proposition 203.

2) Draft Rule R9-17-101(18) defines "Public Place." A.R.S. § 36-2802(C)(2), a new statute created by Proposition 203, specifically does not authorize smoking marijuana "in any public place." The term "public place" is not defined in any of the statutes enacted by Proposition 203.

   A.R.S. § 36-2803 is a new statute enacted by Proposition 203 giving the Department of Health Services rulemaking authority to pass rules for certain enumerated areas. These areas are: a) the manner for considering petitions from the public to add debilitating medical conditions; b) establishing the form and content of registration applications; c) the manner in which applications for registry identification will be governed; and d) governing dispensaries for the purpose of protecting against diversion and theft. This new statute did not give the Department of Health Services authority to define terms as they relate to criminal statutes. We believe the defining of the term "public place" in the rules is not authorized.

3) Draft Rule R9-17-202(F)(5)(f) and (g) describe certain statements required of physicians before a registry identification card for a qualifying patient or designated caregiver is issued. These statements include that the physician reviewed all prescription and non-prescription medications and supplements

used by the patient and that the physician has explained the potential risks and benefits of using medical marijuana with the patient. We object to these requirements for two reasons: a) requiring disclosure of what a physician has or has not discussed with a patient interferes with doctor/patient confidentiality, and b) we know of no other treatment that requires such written statements to the State before a patient may avail himself of the treatment. Again this requirement does not further the purpose of Proposition 203, was not passed by a three-fourths vote of the legislature, and is therefore unconstitutional.

4) Draft Rule R9-17-302(A), as well as others, requires each principal officer or board member of a dispensary to have been an Arizona resident for two years.

   We repeat our stance that this provision does not further the purpose of Proposition 203, was not passed by a three-fourths vote of the legislature, and is therefore unconstitutional. We further point out that, even if it was constitutional under the cited article of the Arizona Constitution, it would violate the Equal Protection Clause of the Fourteenth Amendment to the Constitution of the United States. That analysis is lengthy and not be appropriate for this comment, but we would be happy to expound upon it at your request.

5) Draft Rule R9-17-302(B)(1)(f), as well as others, requires any principal officer or board member to disclose, among other things, whether he is a physician making qualifying patient recommendations, has not filed a tax return in the past, is in default on a student loan, has failed to pay court-ordered child support, or is a law enforcement officer.

   We reiterate our previous statements that such a provision is not constitutionally authorized.

6) Draft Rule R9-17-302(B)(16) requires a dispensary to present, with its application for a certificate, a business plan demonstrating the on-going viability of the dispensary as a non-profit organization.

   Beyond our previous statements that such a provision is not constitutionally authorized, it is impractical because it requires a business to show it can flourish before it starts. Medical marijuana dispensaries will be new to Arizona. The demand for medical marijuana is unknown. It is impossible under these circumstances for any new business to demonstrate that it will be viable until demand is known.

7) Draft Rule R9-17-307(C) makes certain requirements on the amount of marijuana that a dispensary must cultivate itself.

No such provision is made in any statute enacted by Proposition 203 and, as we have previously detailed, is not constitutionally authorized.

8) Draft Rule R9-17-315 addresses security of dispensaries. Section (C)(1)(c) of the rule requires electronic monitoring including the capability of remote viewing. Draft Rule R9-17-306(B) requires a dispensary to provide the Department of Health Services with authorized remote access to that electronic monitoring.

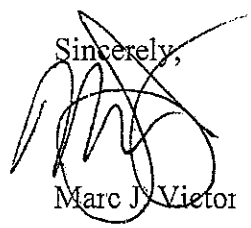
A.R.S. § 36-2806(C), a new statute enacted by Proposition 203, only requires that a dispensary "implement appropriate security measures to deter and prevent the theft of marijuana and unauthorized entrance into areas containing marijuana." A.R.S. § 36-2806(H) provides that "dispensaries are subject to reasonable inspection by the Department."

The Draft Rule has two significant problems. First, it requires remote viewing. Remote viewing will not deter or prevent theft; it just provides the opportunity to watch if a theft is occurring. Good locks and a premium alarm system would be appropriate to deter or prevent theft, but remote viewing does not further the purpose of Proposition 203.

Next, and more significant, we do not believe "reasonable inspection" includes constant remote viewing. Certainly, regular or announced inspections are appropriate. Perhaps surprise inspections based on some level of suspicion would be appropriate. Requiring constant remote video monitoring goes far beyond "reasonable inspection," does not further the purpose of Proposition 203, and probably is an unreasonable search prohibited by the Fourth amendment to the Constitution of the United States and Article II, § 8 of the Arizona Constitution.

We hope you take our comments as they are intended; as constructive commentaries on proposals that may make the rules ultimately promulgated by the Department of Health Services comply with the laws and Constitution of Arizona. We would be happy to expound on any areas you may desire additional comment.

Sincerely,



Marc J. Victor